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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

U.S.S.C.

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FORM ~~10-K~~ 10-K ARIS

(Mark one)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934

Commission File Number 0-21180

**CELLEGY PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

California  
(State or other jurisdiction of  
incorporation or organization)

82-0429727  
(I.R.S. Employer  
Identification No.)

349 Oyster Point Boulevard, Suite 200,  
South San Francisco, California  
(Address of Principal Executive Offices)

94080  
(zip code)

Registrant's telephone number, including area code: (650) 616-2200

PROCESSED

Securities registered pursuant to Section 12(b) of the Act:

None

(Title of each class)

Nasdaq National Market(Name of each exchange on  
which registered)

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THOMSON  
FINANCIAL

Securities registered pursuant to Section 12(g) of the Act:

(Title of class)

Common Stock, no par value

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES X NO     

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of March 5, 2002 was \$74,196,080 based on the closing price for the common stock on The Nasdaq Stock Market on such date. This calculation does not include a determination that persons are affiliates or non-affiliates for any other purpose.

The number of shares of common stock outstanding as of March 5, 2002 was 17,304,976.

**DOCUMENTS INCORPORATED BY REFERENCE**

The information called for by Part III is incorporated by reference to the definitive Proxy Statement for the Annual Meeting of Shareholders of the Company which will be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2001.

**CELLEGY PHARMACEUTICALS, INC.**  
**10-K Annual Report**

**For the Fiscal Year Ended December 31, 2001**

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Unless the context otherwise requires, the terms "we", "our", and "Cellegy" refer to Cellegy Pharmaceuticals, Inc., a California corporation, and its subsidiaries.

Anogesic and Celledirm are our registered trademarks. Cellegesic, Tostrex, Tostrelle, and Rectogesic are our trademarks. We also refer to trademarks of other corporations and organizations in this document. Cellegy recently began using Cellegesic in place of Anogesic for its lead product following discussions with the FDA recommendation during its review of our New Drug Application.

## PART I

### ITEM 1: BUSINESS

Cellegy Pharmaceuticals, Inc. ("Cellegy" or the "Company"), incorporated in California in 1989, is a specialty biopharmaceutical company engaged in the development of prescription drugs and skin care products. Our prescription products are directed towards the treatment of gastrointestinal disorders, sexual dysfunction of both men and women, and selected conditions affecting women's health.

Cellegy's lead product candidate, Cellegesic<sup>TM</sup> (nitroglycerin ointment), formerly referred to as Anogesic(R), is under review by the FDA for the treatment of chronic anal fissures, a painful condition which, in the absence of an approved drug therapy, often requires surgery. We filed the Cellegesic New Drug Application (NDA) with the FDA in June 2001, and an amendment to the NDA was filed in November 2001 including data from a second Phase III clinical study using Cellegesic to treat pain associated with chronic anal fissures. In August 2001, we submitted a Marketing Authorization Application (MAA) to the Medicines Control Agency (MCA) in the United Kingdom requesting approval of Rectogesic<sup>TM</sup> (nitroglycerin ointment) for the treatment of anal fissures. Rectogesic is a product similar in formulation to Cellegesic. In addition, a New Drug Submission (NDS) for Cellegesic marketing approval will be filed by the end of the first quarter of 2002 with the Therapeutic Products Programme (TPP) in Canada. For all of these registrations, Cellegy submitted expert reports and supportive data from the Australian regulatory package for Rectogesic<sup>TM</sup> which was approved by the Australian Therapeutic Goods Administration (TGA) and has been successfully marketed in Australia since early 1999. Cellegy is also conducting two Phase II clinical trials using Cellegesic to determine its effect on the symptoms of hemorrhoids. Hemorrhoids afflict an estimated 22 million people annually in the United States, Europe and Japan, according to published data.

Cellegy's second lead product candidate, Tostrex<sup>TM</sup> (testosterone gel), is for the treatment of male hypogonadism, which usually results in diminished sexual function, lethargy and, in severe cases, reduced bone and muscle mass in men. Based on positive results achieved in an analysis of the majority of patients in the pivotal Phase III trial in November 2001, Cellegy completed patient enrollment and plans to file an NDA during the second quarter of 2002. In addition to Tostrex, Cellegy is developing a second transdermal testosterone gel, Tostrelle<sup>TM</sup>, for the treatment of female sexual dysfunction in postmenopausal women. Testosterone deficiency in women frequently leads to diminished libido, decreased bone and muscle mass and reduced energy levels. Tostrelle has successfully completed two Phase I/II clinical studies and Cellegy expects to begin an advanced Phase II/III study by the end of the first quarter of 2002.

In November 2001, Cellegy acquired Vaxis Therapeutics Corporation ("Vaxis" or "Cellegy Canada"), a private Canadian company based in Kingston, Ontario. This acquisition expands our pipeline of products for the treatment of sexual dysfunction in males and females and complements our current products. In addition to product candidates for the treatment of sexual dysfunction, the Vaxis product pipeline consists of nitroglycerin and other nitric oxide donors for the treatment of various disorders including: Reynaud's Disease, Restless Leg Syndrome, prostate cancer and other potential indications. We have recently expanded our research to capitalize on the scientific expertise of Cellegy Canada's scientists.

Cellegy's research and development programs also focus on inflammation and second generation products for anorectal diseases. In the area of inflammation, our scientists have discovered a family of compounds that we have named CELLEDIRM. CELLEDIRM-based products may be useful in reducing inflammation associated with a number of skin, mucous membrane and gastrointestinal conditions.

This Annual Report includes forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are not historical facts, but rather are based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. Words such as "believes," "anticipates," "expects," "intends" and similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. Our "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains many such forward-looking statements. These forward-looking statements are not guarantees of future performance and

concern matters that involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements. These risks and uncertainties include those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Operating Results" and elsewhere in this Annual Report. Except as required by law, we undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that may arise after the date of this Annual Report. Actual events or results may differ materially from those discussed in this Annual Report.

### **Marketing and Commercialization Strategy**

Cellegy intends to become a leader in the development and marketing of selected specialty biopharmaceutical products that are directed towards the treatment of gastrointestinal disorders, sexual dysfunction of both men and women, and conditions affecting women's health. Key elements of our related business and commercialization strategy include the following:

- *Self-Marketing to Specialty Physician Markets in United States.* We plan to market Cellegesic to a targeted audience of key physician specialists, principally Colon and Rectal Surgeons, Gastroenterologists ("GI's") and Obstetrician-Gynecologists ("OB-GYNs"), through the establishment of our own sales force. We plan to seek larger pharmaceutical partners to assist in the promotion of the product to broader physician audiences. Cellegy intends to commercialize Tostrex through co-promotion agreements with partners in the United States. We plan to outlicense the overseas rights for products we develop in exchange for upfront and milestone payments, as well as royalties on sales.
- *Marketing and Sales Agreement with Ventiv Health.* We announced a comprehensive agreement with Ventiv Health, Inc. ("Ventiv"), a contract sales organization, in August 2001. Under the control and direction of Cellegy, Ventiv will provide certain sales and marketing services relating to the anticipated launch of Cellegesic, including hiring a sales force of approximately 75 representatives. Ventiv will advance up to \$10 million, the amount and timing depending on various circumstances, to Cellegy to cover pre-launch and launch expenses. In return, the agreement provides Ventiv with a share of Cellegesic profits through a multi-royalty stream towards the end of the six-year agreement period.
- *Acquisition of Complementary Products and Companies.* As was done with the acquisitions of Vaxis in Canada in November 2001, of Rectogesic from Quay Pharmaceuticals Pty Ltd ("Quay") in Australia in June 2000, and of Cellegesic from Neptune Pharmaceuticals ("Neptune") in the United States in December 1997, we intend to acquire other products, technologies or companies with products and distribution capabilities consistent with our commercial objectives.
- *Manufacturing.* Cellegy has established a long term agreement with PanGeo Pharma Inc., ("PanGeo") an FDA approved contract manufacturing company based in Canada. PanGeo has successfully manufactured Cellegesic, Tostrex and Tostrelle for our clinical trials and will be the commercial manufacturer for these products, when approved.
- *Distribution.* Cellegy has entered into a distribution agreement for Rectogesic in South Korea and intends to contract additional distributors in Asia, Latin America and the Middle East.

### **Marketed Skin Care Products**

Cellegy has completed development of certain consumer skin care and cosmeceutical products, including skin barrier repairing/fortifying moisturizers, skin protectants and anti-aging lotions and creams. We are currently marketing our C79 Intensive Moisturizer formulation to a major specialty retailer which incorporates C79 into hand cream products. Our revenues from sales of these products totaled \$660,000 in 2001 and have totaled about \$3,400,000 million since product introduction late in 1998.

## Products Under Development

### *Prescription Products*

#### *Cellegesic (nitroglycerin ointment for Treatment of Anal Fissures and Hemorrhoids)*

Cellegy's leading product candidate is Cellegesic, a topical, nitroglycerin-based prescription product for the treatment of anal fissures and hemorrhoids. Anal fissures are painful tears in the lining of the anal mucosa, a condition afflicting men and women of all age groups. Of the over 600,000 new cases of anal fissures occurring each year in the United States, Europe and Japan, many of these chronic cases require painful and expensive surgery, a procedure that sometimes leaves patients incontinent. Hemorrhoids are dilated, swollen veins and tissue located either in the anal canal or at the margin of the anus. In the United States alone, there are approximately 9 million people who suffer from hemorrhoids each year. Both conditions are characterized by an increase in intra-anal pressure, which has been shown to be effectively reduced by the application of Cellegesic.

Current drug therapies include anesthetics and anti-inflammatory agents that only partially relieve the symptoms of these conditions. Even though current treatments are only partially effective, prescription product sales currently used to treat anal fissures and hemorrhoids have been estimated to be approximately \$500 million annually in the United States, Europe and Japan. Surgical procedures and hospitalization stays related to these conditions represent a substantial additional cost to the healthcare systems.

Cellegesic is a proprietary formulation that includes nitroglycerin, a drug that has been used for many years in the treatment of angina pectoris and certain other heart diseases. Several previous third party studies reported that nitroglycerin, once administered to the anal canal, causes relaxation of the sphincter muscle and helps to relieve pain and promote healing of the anal fissure in most patients.

We completed an initial Phase III clinical trial using Cellegesic for the treatment of anal fissures and announced the results in November 1999. The trial did not demonstrate a statistically significant rate of healing in comparison to placebo, but did show rapid and significant pain reduction. Based on this outcome, we initiated a second Phase III trial in 2000 to confirm the drug's ability to reduce fissure pain, the primary trial endpoint, with healing of chronic anal fissures as a secondary endpoint.

The second Phase III clinical trial, which included 229 patients in several study centers in the United States and overseas, was completed in September 2001. Patients received either of two strengths of Cellegesic or placebo administered on a daily basis over an eight-week treatment period. The patient's pain scores were tabulated and the patients were examined to determine whether the fissure had healed. Positive results were achieved in the primary endpoint, which was pain reduction of chronic anal fissures. Statistical significance was not achieved in healing, the secondary endpoint.

In June 2001, we completed patient enrollment and filed an NDA with the FDA requesting marketing approval of Cellegesic for the treatment of pain associated with chronic anal fissures. We amended the NDA upon completion of the second Phase III anal fissure pain study in November 2001. The decision to file the NDA earlier than previously contemplated followed a meeting with the FDA at which Cellegy re-reviewed the results of its initial Cellegesic Phase III clinical trial and presented summary data from several trials conducted with nitroglycerin ointment by investigators around the world, as well as various other materials. Submitting the NDA before completion of the second Phase III trial may not necessarily reduce the period of time during which the FDA reviews the filing and may have no effect on the regulatory review period. There can be no assurances that the NDA filing for Cellegesic will be approved, or that earlier filing of the NDA will result in earlier product approval.

In addition to the above mentioned fissures trial, Cellegy has two Phase II clinical trials underway for various complications of hemorrhoids. Cellegesic is protected by two domestic patents, both of which have been issued, the most recent in December 1997. Similar Canadian and European patents have been issued and numerous patent applications have been filed in most major overseas markets.

*Tostrex (testosterone gel for male hormone replacement therapy)*

Cellegy is currently developing a transdermal testosterone gel to treat male hypogonadism, or below normal levels of the sex hormone testosterone. Low levels of testosterone can result in lethargy, depression and a decline in libido. In severely deficient cases, loss of muscle mass and bone density can occur. Approximately 5 million men in the United States, primarily in the aging (over 40) male population group, have lower than normal levels of testosterone. Male hypogonadism is the first indication for which we will seek regulatory approval in the United States. Subsequently, testosterone replacement may be used for "male andropause," a potentially greater market.

There are a number of companies currently marketing testosterone in several different product forms in domestic and international markets. Cellegy believes that a significant market opportunity exists for an improved product, as the side effects and patient inconveniences associated with many of the currently marketed products have limited their use to less than 5% of potential patients. Current product forms include orals, injectables, transdermal patches and a testosterone gel launched in 2000. The leading patch products are sold at prices averaging about \$1,000 per year per patient with one other gel product priced at over \$3,500 per year.

Cellegy's proprietary testosterone gel product candidate is transparent, rapid-drying and non-staining. It is designed as a once-a-day application from a unique metered dose dispenser to relatively small areas of the skin. Based on successful Phase II dose ranging clinical studies which demonstrated Tostrex's ability to deliver testosterone into the bloodstream, we began a pivotal Phase III clinical trial designed to restore normal levels of testosterone in men with testosterone deficiency. The trial, including 201 patients at several study centers in the United States was successfully completed and positive results were announced in November 2001. Cellegy now expects to file an NDA early in the second quarter of 2002.

*Tostrelle (testosterone gel for female hormone replacement therapy)*

Normal blood concentrations of testosterone in women range from 10 to 20 times less than that of men. Nevertheless, in both sexes, testosterone plays a key role in building muscle tissue or bone, and in maintaining sexual drive. In women, the ovaries and adrenal glands continue to synthesize testosterone after menopause, although the rate of production may diminish by as much as 50%. Approximately 15 million women in the United States suffer from symptoms of testosterone deficiency. At the present time, there are no approved products for the treatment of this condition.

Based on the results of pharmacokinetic studies in men receiving Tostrex, Cellegy's scientists were able to estimate the proper dosage of testosterone required to achieve normal pre-menopausal hormone levels in postmenopausal women. The result is Cellegy's Tostrelle, a product designed to restore normal testosterone levels in hormone deficient women.

Cellegy has successfully completed two Phase I/II pharmacokinetic studies in which we determined the proper dose necessary to restore normal testosterone levels to normally menopausal and surgically-induced menopausal women. Based on these results, and a meeting with the FDA to discuss advanced trial protocols, we now intend to initiate a Phase II/III clinical study in the first quarter of 2002.

## **Technology**

### *Current Research Programs*

Cellegy's research and development programs focus on nitric oxide pharmacology, inflammation and nitric oxide treatments for anorectal and gastrointestinal diseases, sexual function and other indications. The recent acquisition of Vaxis has significantly broadened Cellegy research and development efforts for the treatment of female sexual dysfunction and male erectile dysfunction, and has also expanded our research into potential oncology treatments.

Cellegy's ongoing research and development efforts in the area of anorectal disease have led to the identification and formulation development of two second generation products for the treatment of anal fissures and hemorrhoids. Early studies showed that these formulations are stable and will be suitable for human clinical testing.

Our overall research efforts in nitric oxide pharmacology have expanded subsequent to the November 2001 acquisition of Vaxis. Based on research efforts at Queen's University at Kingston, we better understand the role of nitric oxide as a signaling molecule in modulating vascular smooth muscle relaxation, perhaps by down-regulating endothelin expression. The significance of this finding is that nitric oxide is capable of reducing vascular tone at a concentration much lower than needed for a direct vaso-dilatation effect, especially in tissues under an abnormally vaso-constrictive state. This discovery presents various potential approaches to treat conditions caused by vaso-constriction, such as peripheral vascular insufficiency found in Raynaud's disease, male erectile dysfunction, and selected aspects of female sexual dysfunction. We plan to verify and validate selected potential therapeutic indications via in vivo animal testing and in pilot human studies.

We are also investigating the role of nitric oxide in modulating cancer cell metastasis induced by hypoxia (low oxygen) and in attenuating pain due to nociceptor activation. Results published in the Journal of National Cancer Institute in December 2001 showed that the administration of nitric oxide to hypoxic cancer cells led to reversal of the metastatic phenotype. Furthermore, nitric oxide can also reverse the development of hypoxia-induced drug resistance cancer phenotype to chemotherapeutic agents. Follow-up experiments since the publication further support the original findings. We will continue to expand upon these original findings with relevant in vitro and in vivo models through the research efforts at the Queen's University and to further explore the ability of nitric oxide to interfere with other nociceptive signaling pathway.

In the area of inflammation, our scientists discovered a family of compounds called CELLEDIRM (Cellegy's Dermal Inflammatory Response Modulators). CELLEDIRM is a group of compounds that have demonstrated in pre-clinical testing a reduction of the inflammation associated with the topical application of drugs and other active substances. Our in-house efforts have also identified anti-inflammatory compounds for the treatment of gastrointestinal and urogenital inflammatory disorders. Based on the safety and in vitro profiling of screened compounds, one compound was selected for further in vivo testing in a relevant model. Preliminary results using an experimental vehicle showed positive effects with the lead candidate and we are planning to conduct additional proof-of-concept studies.

In March 1994, Cellegy entered into an exclusive, worldwide, royalty bearing license agreement with the University of California (the "University") for patent rights, jointly held by the University and Cellegy, relating to certain drug delivery technologies. Cellegy agreed to pay a licensing and maintenance fee each year until Cellegy is commercially selling a product using the licensed technology. We are currently in discussion with the University to terminate, on mutually acceptable terms, the license agreement for patent rights relating to drug delivery technologies.

Cellegy's research and development expenses were \$14,098,000 in 2001, \$9,574,000 in 2000, and \$7,965,000 in 2001, 2000 and 1999. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

#### **Patents and Trade Secrets**

Cellegy has 19 issued United States patents, more than 70 issued foreign patents, and over 70 pending patent applications. Two issued United States patents, 22 issued foreign patents, and more than 10 pending patent applications relate to Cellegy's Cellegesic product for the treatment of anal fissures. One issued United States patent, and 16 pending patent applications relate to our Tostrex and Tostrelle products. Four pending United States patent applications and 21 foreign patent applications relate to possible backup compounds for our Cellegesic product. In addition, as part of Cellegy's acquisition of Vaxis, Cellegy gained rights to 3 issued United States patents, 2 issued foreign patents, and more than 25 pending patent applications. Additional patent applications are being prepared for filing that will cover methods or products currently under development. Corresponding patent applications for most of Cellegy's issued United States patents have been filed in countries of importance to us located in major world markets, including certain countries in Europe, Australia, South Korea, Japan, Mexico and Canada.

Our policy is to protect our technology by, among other things, filing patent applications for technology that we consider important to the development of our business. We intend to file additional patent

applications, when appropriate, relating to our technology, improvements to our technology and to specific products that we develop. It is impossible to anticipate the breadth or degree of protection that any such patents will afford, or whether we can meaningfully protect our rights to our unpatented trade secrets. Cellegy also relies upon unpatented trade secrets and know-how, and no assurance can be given that competitors will not independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our rights to our unpatented trade secrets. It is our policy to require our employees to execute an invention assignment and confidentiality agreement upon employment. Our consultants are required to execute a confidentiality agreement upon the commencement of their consultancy. Each agreement provides that all confidential information developed or made known to the employee or consultant during the course of employment or consultancy will be kept confidential and not disclosed to third parties except in specific circumstances. The invention assignment generally provides that all inventions conceived by the employee shall be the exclusive property of Cellegy. In addition, it is our policy to require collaborators and potential collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection of our trade secrets.

Our success depends, in part, on our ability to obtain patent protection for our products and methods, both in the United States and in other countries. The patent position of companies engaged in businesses such as our business generally is uncertain and involves complex legal and factual questions. There is a substantial backlog of patent applications at the United States Patent and Trademark Office ("USPTO"). Patents in the United States are issued to the party that is first to invent the claimed invention. Since patent applications in the United States currently can be maintained in secrecy until patents issue, we cannot be certain that Cellegy was the first inventor of the invention covered by our pending patent applications or patents or that we were the first to file patent applications for such inventions. Further, issued patents can later be held invalid by the patent office or by a court. There can be no assurance that any patent applications relating to our products or methods will issue as patents, or, if issued, that the patents will not be challenged, invalidated, or circumvented or that the rights granted thereunder will provide a competitive advantage to us.

In addition, many other entities are engaged in research and product development efforts in fields that may overlap with our currently anticipated and future products. A substantial number of patents have been issued to such companies, and such companies may have filed applications for, or may have been issued patents or may obtain additional patents and proprietary rights relating to, products or processes competitive with those of Cellegy. Such entities may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by us. These rights may prevent us from commercializing technology, or may require us to obtain a license from the entity to practice the technology. There can be no assurance that the manufacture, use or sale of any of our product candidates will not infringe patent rights of others. There can be no assurance that we will be able to obtain any such licenses that may be required on commercially reasonable terms, if at all, or that the patents underlying any such licenses will be valid or enforceable.

Moreover, the laws of certain foreign countries do not protect intellectual property rights relating to United States patents as extensively as those rights are protected in the United States. The issuance of a patent in one country does not assure the issuance of a patent with similar claims in another country, and claim interpretation and infringement laws vary among countries, so the extent of any patent protection is uncertain and may vary in different countries. As with other companies in the pharmaceutical industry, we are subject to the risk that persons located in other countries will engage in development, marketing or sales activities of products that would infringe our patent rights if such activities were in the United States.

Several of Cellegy's products and product candidates, such as Cellegesic, Tostrex and Tostrelle are based on existing molecules with a history of use in humans but which are being developed by us for new therapeutic uses or in novel delivery systems which enhance therapeutic utility. We cannot obtain composition patent claims on the compounds themselves, and will instead need to rely on patent claims, if any, directed to use of the compound to treat certain conditions or to specific formulations. This is the case,



for example, with our United States patents relating to Cellegesic and Tostrex. Such method-of-use patents may provide less protection than a composition-of-matter patent, because of the possibility of "off-label" use of the composition. Cellegy may not be able to prevent a competitor from using a different formulation or compound for a different purpose. No assurance can be given that any additional patents will be issued to us, that the protection of any patents that may be issued in the future will be significant, or that current or future patents will be held valid if subsequently challenged.

### **Product Acquisitions**

On November 27, 2001, Cellegy acquired Vaxis Therapeutics Corporation, a private Canadian company. Vaxis, subsequently renamed Cellegy Canada, is a wholly-owned research and development subsidiary with pre-eminent scientists focusing in the areas of sexual dysfunction, peripheral vascular disorders and nitric oxide pharmacology. This research is in line with our goal of expanding our pipeline of products and protecting our patents. The purchase price of \$4.1 million consisted of 533,612 shares of our common stock and \$142,000 in cash. There are potential future earn-out considerations payable by Cellegy in stock or cash tied to revenues generated by Vaxis' technologies.

In June 2000, Cellegy acquired Quay Pharmaceuticals, an Australian company marketing Rectogesic, a nitroglycerin ointment product similar to Cellegesic. The acquisition cost totaled \$1,835,000, consisting of 169,224 shares with a value of \$977,000, 171,146 warrants to purchase common stock with a value of \$489,000, and cash payments of \$369,000. Cellegy will continue to self-market Rectogesic in Australia through its wholly-owned Cellegy Australia subsidiary and plans to sell Rectogesic through distributors in the Pacific Rim countries and potentially other countries around the world.

In December 1997, Cellegy acquired patent and related intellectual property rights relating to Cellegesic, a topical product candidate for the treatment of anal fissures and hemorrhoids, from Neptune Pharmaceuticals. Pursuant to the purchase agreement, we issued 462,809 shares of common stock to Neptune in 1997. The agreement calls for a series of additional payments, payable in shares of common stock, upon successful completion of various milestones tied to clinical trial results and commercialization of Cellegesic in domestic and foreign markets. Two research milestones were achieved during 2001 resulting in the issuance of 104,113 Cellegy shares for a total value of \$750,000. Future potential milestones, payable in Cellegy common stock, could result in the issuance of up to an additional 1,283,887 shares of Cellegy common stock based on the closing price of Cellegy stock at the time of issuance. The agreement does not provide for the payment by Cellegy of any future product royalties to Neptune in connection with Cellegesic revenues.

### **Government Regulation**

**FDA Requirements for Human Drugs.** The research, testing, manufacturing, labeling, distribution, and marketing of drug products are extensively regulated by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous FDA regulation. The Food, Drug and Cosmetic Act (the "FD&C Act") and the regulations promulgated thereunder, and other federal and state regulations govern, among other things, the research, development, testing, manufacture, distribution, storage, record keeping, labeling, advertising, promotion and marketing of pharmaceutical products. The process of developing and obtaining approval for a new pharmaceutical product within this regulatory framework requires a number of years and the expenditure of substantial resources. There can be no assurance that necessary approvals will be obtained on a timely basis, if at all. Moreover, additional government regulations may be established that could prevent or delay regulatory approval of our products. Delays in obtaining regulatory approvals could have a material adverse effect on us. If we fail to comply with applicable regulatory requirements for marketing drugs, or if our cosmeceutical products are deemed to be drugs by the FDA, we could be subject to administrative or judicially imposed sanctions such as warning letters, fines, products recalls or seizures, injunctions against production, distribution, sales, or marketing, delays in obtaining marketing authorizations or the refusal of the government to grant such approvals, suspensions and withdrawals of previously granted approvals, civil penalties and criminal prosecution of Cellegy, our officers or our employees.

The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include: (i) preclinical laboratory tests, animal studies and formulation studies; (ii) the submission

to the FDA of an Investigational New Drug Application ("IND"), which must become effective before clinical testing may commence; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its proposed indication; (iv) the submission of a New Drug Application ("NDA") to the FDA; and (v) FDA review and approval of the NDA prior to any commercial sale or shipment of the drug. Compounds must be produced according to the FDA's current Good Manufacturing Practice ("GMP") requirements, and preclinical tests must be conducted in compliance with the FDA's Good Laboratory Practice regulations. The results of preclinical testing are submitted to the FDA as part of an IND. The FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials may not commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials to support NDAs are typically conducted in three sequential phases, which may overlap. In Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug generally is tested to assess metabolism, pharmacokinetics, pharmacological action and safety, including side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. Phase II usually involves studies in a limited patient population to (i) determine the efficacy of the drug for a specific indication, (ii) determine dosage tolerance and optimal dosage and (iii) identify possible short-term adverse effects and safety risks. If a compound is found to be effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical study sites. A clinical trial may combine the elements of more than one phase, and typically two or more Phase III studies are required. There can be no assurance that Phase I, Phase II or Phase III testing will be completed within any specific time period, if at all.

Cellegy's prescription products, and our ongoing research and clinical activities such as those relating to Cellegesic, Tostrex, and Tostrelle are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. Extensive current pre-clinical and clinical testing requirements and the regulatory approval process of the FDA in the United States and of certain foreign regulatory authorities, or additional future government regulations, could prevent or delay regulatory approval of Cellegy's products. Disagreements with one or more regulatory authorities may occur in the future, and one or more of our ongoing or planned clinical trials could be delayed or repeated in order to satisfy regulatory requirements. Sales of Cellegy's products outside the United States are subject to regulatory requirements governing clinical trials and marketing approval. These requirements vary widely from country to country and could delay introduction of Cellegy's products in those countries.

Our clinical trial results are very difficult to predict in advance, and failure of one or more clinical trials could adversely affect our business and our stock price. Before we obtain regulatory approval for the commercial sale of most potential drug products, we must demonstrate through pre-clinical studies and clinical trials that the product is safe and efficacious for use in the clinical indication for which approval is sought. We cannot assure you that the FDA or other international regulatory authorities will permit us to undertake any future clinical trials for potential products or to continue any of the current clinical trials. To date, except for our NDA relating to Cellegesic, we have not sought FDA approval to distribute any products. Moreover, results of pre-clinical studies and early clinical trials may not be good predictors of results that will be obtained in later-stage clinical trials. We cannot assure you that Cellegy's present or future clinical trials will demonstrate the results required for approval to market these potential products or even to continue with additional clinical development. Because of the independent and blind nature of certain human clinical testing, there will be extended periods during the testing process when we will have only limited or no access to information about the status or results of the tests. Other pharmaceutical companies have believed that their products performed well in early tests, only to find that later tests, including Phase III clinical trials, were inadequate or unsatisfactory, or that FDA Advisory Committees have declined to recommend approval of the drugs, or that the FDA itself refused approval,

with the result that such companies' stock prices have fallen precipitously. If the FDA delays approval of, or fails to approve, our NDA for Cellegesic or planned NDA for Tostrex, our price would be materially and adversely affected.

*New Drug Applications.* After completion of the required clinical testing, generally an NDA is submitted. FDA approval of the NDA (as described below) is required before marketing may begin in the United States. The NDA must include the results of extensive clinical and other testing and the compilation of data relating to the product's chemistry, pharmacology and manufacture, the cost of all of which is substantial. The FDA reviews all NDAs submitted and may request more information before it accepts the filing. The review process is often extended significantly by FDA requests for additional information or clarification. The FDA may refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. During the review process, the FDA generally will conduct an inspection of the relevant drug manufacturing facilities and clinical sites to ensure that the facilities are in compliance with applicable Good Manufacturing Practices (GMP) requirements. If FDA evaluations of the NDA application, manufacturing facilities, and clinical sites are favorable, the FDA may issue either an approvable letter or a not approvable letter, which contains a number of conditions that must be met in order to secure approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approvable letter, authorizing commercial marketing of the drug for certain specific indications. If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter, outlining the deficiencies in the submission and often requiring additional testing or information. Notwithstanding the submission of any requested additional data or information in response to an approvable or not approvable letter, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. Even if FDA approval is obtained, a marketed drug product and its manufacturer are subject to continual review and inspection, and later discovery of previously unknown problems with the product or manufacturer may result in restrictions or sanctions on such product or manufacturer, including withdrawal of the product from the market.

*Manufacturing.* Each domestic drug manufacturing facility must be registered with the FDA. Domestic drug and, to a lesser extent, cosmetic manufacturing establishments are subject to routine inspection by the FDA and other regulatory authorities and must comply with GMP requirements (albeit less extensive ones for cosmetics than for drugs), and any applicable state or local regulatory requirements. We intend to use contract manufacturers that operate in conformance with these requirements to produce our compounds and finished products in commercial quantities. There can be no assurance that manufacturing or quality control problems will not arise at the manufacturing plants of our contract manufacturers or that such manufacturers will be able to maintain the compliance with the FDA's GMP requirements necessary to continue manufacturing our products.

*Foreign Regulation of Drugs.* Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities may be necessary in foreign countries before the commencement of marketing of the product in such countries. The approval procedures vary among countries, can involve additional testing, and the time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. We expect to rely principally on corporate partners, licensees and contract research organizations, along with our expertise, to obtain governmental approval in foreign countries of drug formulations utilizing our compounds.

*Other Government Regulation.* In addition to regulations enforced by the FDA, Cellegy is also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other similar federal and state laws regarding, among other things, occupational safety, the use and handling of radioisotopes, environmental protection and hazardous substance control. Although we believe that we have complied with these laws and regulations in all material respects and have not been required to take any action to

correct any noncompliance, there can be no assurance that Cellegy will not be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, chemicals, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, Cellegy could be held liable for any damages that result and any such liability could exceed our resources.

*Health Care Reform.* In the United States, there have been, and Cellegy expects there will continue to be, a number of federal and state proposals to implement cost controls and other health care regulatory measures. Future legislation could result in a substantial restructuring of the health care delivery system. While we cannot predict whether any legislative or regulatory proposals will be adopted or the effect such proposals may have on our business, the uncertainty of such proposals could have a negative effect on our ability to raise capital and to identify and reach agreements with potential partners, and the adoption of such proposals could have an adverse effect on Cellegy. In both domestic and foreign markets, sales of our therapeutic products, if any, will depend in part on the availability of reimbursement from third-party payors. Third-party payors and others increasingly are challenging the prices charged for medical products and services. There can be no assurance that our products will be considered cost effective or that reimbursement will be available. We cannot predict the outcome of any government or industry reform initiatives or the impact thereof on our financial position or results of operations.

### **Competition**

The pharmaceutical and cosmeceutical industries are characterized by extensive research efforts and rapid and significant technological changes. In the development and marketing of topical prescription drugs, cosmeceutical and skin care products, and drug delivery systems, Cellegy faces intense competition. Cellegy is much smaller in terms of size and resources than many of its competitors in the United States and abroad, which include, among others, major pharmaceutical, cosmetic, chemical, consumer product, and biotechnology companies, specialized firms, universities and other research institutions. Cellegy's competitors may succeed in developing technologies and products that are safer, more effective or less costly than any which are being developed by us that would render our technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, clinical production and marketing capabilities and regulatory experience than us. In addition, Cellegy's products are subject to competition from existing products. For example, Cellegy's Tostrex product, if commercialized, is expected to compete with two currently marketed transdermal patch products sold by Johnson and Johnson and Watson Pharmaceuticals and one transdermal testosterone gel product marketed by Unimed/Solvay. Cellegy's Cellegesic product, if commercialized, is expected to compete with over-the-counter products, such as Preparation H marketed by American Home Products, and various other prescription products. As a result, we cannot assure you that Cellegy's products under development will be able to compete successfully with existing products or innovative products under development by other organizations.

Therapies for sexual dysfunction and women's health products represent a very large market opportunity, especially as the overall population continues to age. As the size of the market continues to grow, the competition will expand. The approval and marketing of competitive products and other products that treat the indications targeted by Cellegy could adversely affect the market acceptance of Cellegy's products. The presence of directly competitive products could also result in more intense price competition than might otherwise exist, which could have a material adverse effect on Cellegy. Cellegy is aware of at least, three other companies developing testosterone replacement products for women and believes that competition will be intense for all of its female and male sexual dysfunction product candidates.

## Employees

As of March 5, 2002, we had 34 full-time and two part-time employees. Twenty-one of these employees, of whom 2 are M.D.'s and another 8 are Ph.D.'s, are engaged in research and development. In addition, we utilize the services of several professional consultants, as well as contract manufacturing and research organizations to supplement our internal staff's activities. None of our employees are represented by a labor union. We have experienced no work stoppages and we believe that our employee relations are good.

## ITEM 2: PROPERTIES

Cellegy currently leases 65,340 square feet of space located in South San Francisco, California. Approximately 33,154 square feet of this space is currently available for sublease. This space was previously subleased over the last two years. Total rental income from rent payments to Cellegy was \$897,000 in 2001. We expect to receive substantially less rental income in 2002 and beyond resulting from the expiration of prior subleases and excess capacity in the office rental market. We believe our current facilities will be adequate for our needs for expansion for at least the next five years.

## ITEM 3: LEGAL PROCEEDINGS

Cellegy is not a party to any material legal proceedings.

## ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our shareholders during the fourth quarter of the year ended December 31, 2001.

## ITEM 4A: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

### MANAGEMENT

The directors and executive officers of Cellegy are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
K. Michael Forrest	58	Chairman, President, Chief Executive Officer and Director
Daniel L. Azarnoff, M.D.	75	Senior Vice President, Clinical and Regulatory Affairs
John J. Chandler	60	Vice President, Corporate Development
A. Richard Juelis	53	Vice President, Finance and Chief Financial Officer
Felix J. Baker, Ph.D. (1)	33	Director
Julian C. Baker	35	Director
Jack L. Bowman (1)	69	Director
Tobi B. Klar, M.D.	47	Director
Ronald J. Saldarini, Ph.D. (2)	62	Director
Alan A. Steigrod (1) (2)	64	Director
Carl R. Thornfeldt, M.D.	50	Director
Larry J. Wells (2)	59	Director

(1) Member of the Compensation Committee. (2) Member of the Audit Committee.

*K. Michael Forrest.* Mr. Forrest became Chairman in May 2000 and has been President, CEO, and a director since December 1996. From January 1996 to November 1996, he served as a biotechnology consultant. From November 1994 to December 1995, he served as President and CEO of Mercator Genetics, a public biotechnology company. From March 1991 to June 1994, he served as President and CEO of Transkaryotic Therapies, Inc., a public biotechnology company. From 1968 to 1991, Mr. Forrest held a series of positions with Pfizer, Inc. and senior management positions with American Cyanamid,

including Vice President of Lederle U.S. and Lederle International. He is a director of INEX Pharmaceuticals, a public company developing anti-cancer products.

*Daniel L. Azarnoff, M.D.* Dr. Azarnoff joined Cellegy as Vice President, Clinical and Regulatory Affairs in October 1997. He became Senior Vice President in July 1999, and in February of 2001 was given the additional responsibility of Medical Director. Since January 1986, Dr. Azarnoff has been President of D.L. Azarnoff Associates and will continue consulting to the industry on a part-time basis. From August 1978 to December 1985, he served as President of Research and Development at G.D. Searle and Co. From July 1967 to August 1978, he was KUMC Distinguished Professor of Medicine and Pharmacology, as well as the Director of the Clinical Pharmacology-Toxicology Center at the University of Kansas Medical Center. Dr. Azarnoff has also served as a member of advisory and expert committees within the Food and Drug Administration, World Health Organization, American Medical Association, National Academy of Sciences and National Institutes of Health. Dr. Azarnoff is a member of The Institute of Medicine of the National Academy of Sciences. He received his M.D. from the University of Kansas Medical School. Dr. Azarnoff was a director of Cibus Pharmaceutical, Oread and Entropin Inc., through 1998, and is currently director of Western Center Clinical Trials.

*John J. Chandler.* Mr. Chandler became Vice President, Corporate Development in May 1998. From January 1995 to March 1998, he served as Vice President, Europe for the Medical Device Division of American Home Products. During 1994, he was Area Director, Europe/Latin America for American Home Products. From 1968 to 1993, he held a series of management and senior management positions with American Cyanamid Company. Mr. Chandler holds an M.B.A. in Marketing from Seton Hall University and a B.S. in Biology from the Queens College of the City University of New York.

*A. Richard Juelis.* Mr. Juelis became Vice President, Finance and Chief Financial Officer in November 1994. From January 1993 to September 1994 he served as Vice President, Finance and Chief Financial Officer for VIVUS, Inc., a publicly traded drug delivery company. From October 1990 to December 1992, he served as Vice President, Finance and Chief Financial Officer at XOMA Corporation, a public biotechnology company. Mr. Juelis has also held domestic and international financial and general management positions for seven years each with Hoffmann-LaRoche and Schering-Plough. He holds a B.S. in Chemistry from Fordham University and an M.B.A. from Columbia University.

*Felix J. Baker, Ph.D.* Dr. Baker became a director in May 2000. He is currently a managing partner of Baker/Tisch Investments. Along with his brother, Julian C. Baker, he co-founded this biotechnology investing partnership with the Tisch Family, which they have managed since 1994. Over the past few years, the Bakers have also partnered with major university and other endowments to create multiple additional funds. Collectively these funds, known as Baker/Tisch Investments, have grown into one of the largest private sources of capital focused on publicly traded life sciences companies. Dr. Baker is a director of Neurogen Corporation, a public pharmaceutical company, and several private companies. He holds a B.S. degree and a Ph.D. in Immunology from Stanford University.

*Julian C. Baker.* Mr. Baker became a director in December 2000. He is currently a managing partner of Baker/Tisch Investments which, as described above, was co-founded by Mr. Baker and his brother. Mr. Baker was employed from 1988 to 1993 by the private equity investment arms of The First Boston Corporation and CSFB, and was a founding employee of The Clipper Group, which managed funds for First Boston and Credit Suisse. Mr. Baker holds an A.B. *magna cum laude* from Harvard University.

*Jack L. Bowman.* Mr. Bowman became a director in December 1996. He is currently a consultant to various pharmaceutical and biotechnology industry groups. From August 1987 to January 1994, he was Company Group Chairman at Johnson & Johnson, where he managed much of its global diagnostic and pharmaceutical businesses. Before then, Mr. Bowman held executive positions with CIBA-Geigy and American Cyanamid, where he had responsibility for worldwide pharmaceutical, medical device and consumer product divisions. He is currently a director of Celgene Corporation, NeoRx Corp., Cell Therapeutics, Inc. and Targeted Genetics, Inc. and is the Chairman of Reliant Pharmaceuticals.

*Tobi B. Klar, M.D.* Dr. Klar became a director in June 1995. She is a physician, board certified in dermatology. Since 1986, Dr. Klar has maintained a private dermatology practice and has served as Co-Chairperson of the Department of Dermatology at New Rochelle Hospital Medical Center, New Rochelle, New York, and Associate Clinical Professor in dermatology at Albert Einstein Medical Center in New York City. Dr. Klar holds a M.D. from the State University of New York.

*Ronald J. Saldarini, Ph.D.* Dr. Saldarini became a director in July 1999, after retiring from Wyeth. He serves on two committees (Military Vaccines, Immunization Finance) at the National Academy of Sciences Institute of Medicine and is a consultant to the Malaria Vaccine Initiative. He is also associated with Naimark and Associates, a consulting firm, which provides service to the healthcare industry. Prior to his board membership, he was the President of Wyeth Lederle Vaccines and Pediatrics, a division of Wyeth from January 1995 to June 1999. He was also President of the Lederle-Praxis Biologicals Division from 1989 through 1994. He has been a member of the National Vaccine Advisory Committee and the National Advisory Commission on Childhood Vaccines. He received his Ph.D. in Biochemistry and Physiology. He is currently director of Idun Pharmaceuticals, Therion Biologics, Alphavax and Medarex, Inc.

*Alan A. Steigrod.* Mr. Steigrod became a director in July 1996. Since January 1996, he has been Managing Director of Newport HealthCare Ventures, which invests in and advises biopharmaceutical companies. From March 1993 to November 1995, he served as President and CEO of Cortex Pharmaceuticals, Inc. From February 1991 to February 1993, he worked as a biotechnology consultant. From March 1981 through February 1991, Mr. Steigrod held a series of executive positions with Glaxo Wellcome, Inc., serving as Chairman of Glaxo's operating committee, as well as on its board of directors. Prior to Glaxo, Mr. Steigrod held a number of senior management positions with Boehringer Ingelheim, Ltd. and Eli Lilly & Co. He is a director of Sepracor Inc., NeoRx Corporation and Lorus Therapeutics.

*Carl R. Thornfeldt, M.D.* Dr. Thornfeldt is a co-founder and a director, as well as a physician, board certified in dermatology. Dr. Thornfeldt served as Chairman from 1996 to July 2000 and as acting CEO from July 1996 to December 1996. In addition, Dr. Thornfeldt served as Vice President, Research and Development from October 1994 until May 1996. Since 1983, Dr. Thornfeldt has maintained a private dermatology practice and is an Assistant Clinical Professor in Dermatology at the University of Oregon Health Sciences Center. He completed his dermatology residency at the University of California, San Diego. He has authored numerous publications and is named as the sole inventor or one of several inventors of over twenty United States patents. Dr. Thornfeldt received his M.D. from the University of Oregon Health Sciences Center.

*Larry J. Wells.* Mr. Wells became a director in 1989. For the past eighteen years, he has been a venture capitalist. He is the President of Wells Investment Group, the General Partner of Quivira Venture Partners, L.P., and the founder of Sundance Venture Partners, L.P. Mr. Wells is a director of Isonics Corporation and Wings America.

Directors hold office until the next annual meeting of shareholders and until their respective successors have been elected and qualified. Executive officers are chosen by and serve at the discretion of the Board of Directors, subject to any written employment agreements with Cellegy.

Standing committees of the Board include an Audit Committee and a Compensation Committee. The Board does not have a nominating committee or a committee performing similar functions.

Messrs. Wells and Steigrod and Dr. Saldarini are the current members of the Audit Committee. Mr. Wells is the current chairman of the Audit Committee. Mr. Steigrod will become chairman effective immediately after the Annual Meeting. The Audit Committee reviews our accounting practices, internal control systems and the fee arrangements with our independent auditors as well as their independence and performance, and meets with our independent auditors concerning the scope and terms of their engagement and the results of their audit. Messrs. Bowman and Steigrod and Dr. Felix Baker are the current members of the Compensation Committee. Dr. Baker will become chairman effective immediately after the Annual Meeting. The Compensation Committee recommends compensation for officers and employees of Cellegy, grants stock options and stock awards under our employee benefit plans, and approves current warrants granted to certain consultants.

## PART II

### ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

#### Price Range of Common Stock

Cellegy's common stock currently trades on The Nasdaq Stock Market under the symbol "CLGY." The following table sets forth the range of high and low sales prices for the common stock as reported on The Nasdaq Stock Market for the periods indicated below.

<u>2001</u>	<u>High</u>	<u>Low</u>
First Quarter .....	\$7.37	4.31
Second Quarter .....	7.75	4.20
Third Quarter .....	7.08	5.01
Fourth Quarter .....	9.15	6.36
<u>2000</u>		
First Quarter .....	\$9.97	\$3.25
Second Quarter .....	8.25	4.69
Third Quarter .....	9.43	7.00
Fourth Quarter .....	8.00	4.38

#### Holdings

As of March 5, 2002, there were approximately 175 shareholders of record excluding beneficial holders of stock held in street name.

#### Dividend Policy

We have never paid cash or declared dividends on our common stock. We do not anticipate that we will declare or pay cash dividends on our common stock in the foreseeable future.



**ITEM 6: SELECTED FINANCIAL DATA**

The following selected historical information has been derived from audited financial statements of Cellegy. The financial information as of December 31, 2001 and 2000 and for each of the three years in the period ended December 31 are derived from audited financial statements. The financial statements, related notes thereto, and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K should be read carefully. The selected data is not intended to replace the financial statements.

(\$000's)	Years ended December 31,				
	2001	2000	1999	1998	1997
<b>Statement of Operations Data:</b>					
Revenues .....	\$ 877	\$ 1,586	\$ 1,045	\$ 832	\$ 828
Costs and expenses .....	<u>21,847<sup>(1)</sup></u>	<u>13,573</u>	<u>10,847</u>	<u>9,266</u>	<u>9,238</u>
Loss from operations .....	(20,970)	(11,987)	(9,802)	(8,434)	(8,410)
Interest income (expense) and other, net .....	<u>1,505</u>	<u>569</u>	<u>501</u>	<u>1,068</u>	<u>556</u>
Net loss .....	(19,465)	(11,418)	(9,301)	(7,366)	(7,854)
Non-cash preferred dividends .....	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>35</u>
Net loss applicable to common shareholders .....	<u>\$(19,465)</u>	<u>\$(11,418)</u>	<u>\$(9,301)</u>	<u>\$(7,366)</u>	<u>\$(7,889)</u>
Basic and diluted net loss per common shareholder .....	<u>\$ (1.26)</u>	<u>\$ (0.91)</u>	<u>\$ (0.85)</u>	<u>\$ (0.73)</u>	<u>\$ (1.18)</u>
Weighted average common shares outstanding .....	15,503	12,542	10,914	10,160	6,670

(1) During the year ended December 31, 2001, we recorded one-time, non-cash charges of \$3,507,134 for in-process research and development associated with the Vaxis acquisition and \$750,000 in non-cash charges for research and development expenses associated with milestone payments to Neptune Pharmaceuticals.

	December 31,				
	2001	2000	1999	1998	1997
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and investments .....	\$ 17,190 <sup>(2)</sup>	\$ 15,923 <sup>(2)</sup>	\$ 16,737	\$ 15,220	\$ 21,726
Total assets .....	22,367	21,259	20,913	19,484	22,751
Deficit accumulated during the development stage .....	(70,377)	(50,912)	(39,494)	(30,192)	(22,826)
Total shareholders' equity .....	\$ 19,845	18,794	15,839	14,218	21,354

(2) Includes restricted cash of \$614,000.

**ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*This Annual Report on Form 10-K includes forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are not historical facts, but rather based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. Words such as "believes," "anticipates," "expects," "intends" and similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. These forward-looking statements are not guarantees of future performance and concern matters that involve risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. These risks and uncertainties include those described in "Factors That May Affect Future Operating Results" and*

*elsewhere in this Annual Report. Except as required by law, we undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that may arise after the date of this Annual Report. Actual events or results may differ materially from those discussed in this Annual Report.*

Cellegy Pharmaceuticals, Inc., a specialty biopharmaceutical company incorporated in California in 1989, is engaged in the development of prescription drugs and skin care products. We are developing several prescription drugs, including Cellegesic, a nitroglycerin-based product for the treatment of anal fissures and hemorrhoids and two transdermal testosterone gel products, Tostrex, for the treatment of male hypogonadism, a condition that afflicts certain men, generally above the age of forty, and Tostrelle, for the treatment of sexual dysfunction in menopausal women.

#### **General**

In December 1997, we completed an asset purchase agreement with Neptune Pharmaceuticals to acquire patent and other intellectual property rights relating to Cellegesic. Cellegesic expenses have been a significant part of Cellegy's spending since the acquisition and are expected to continue to be significant during the remainder of 2002 as a result of two Phase II clinical trials for the treatment of hemorrhoids. We will incur significant expenses associated with pre-launch activities and on the on-going marketing and sales of Cellegesic, if approved.

In September 1998, we began initial shipments and product sales of C79 Intensive Moisturizing formulation to Gryphon Development Inc., ("Gryphon") the product development arm of a major specialty retailer. C79 is a key ingredient in a line of healing hand creams sold at most of the specialty retailer's stores in the United States.

In June 2000, we acquired all of the assets of Quay Pharmaceuticals, an Australian pharmaceutical company producing Rectogesic, a drug similar to Cellegesic. The acquired assets consisted of Quay's inventory, other tangible assets, and purchased technology. The purchase price of \$1,835,000 included 169,224 shares of our common stock paid to Quay with an estimated value of \$977,000, warrants to purchase 171,146 shares of common stock with an estimated value of \$489,000, and cash payments of \$369,000. The purchase price was allocated to net tangible assets of \$97,000, purchased technology of \$770,000, and goodwill of \$968,000 based on their estimated fair values on the acquisition date. Purchased technology and goodwill have been amortized over three and ten years, respectively. We evaluated this acquisition under the new accounting pronouncements (discussed below), Statement 141 and 142. Under the new guidance effective January 1, 2002, goodwill will no longer be amortized and will be evaluated for impairment.

In June 2001, we completed a private placement of approximately 2.7 million shares of our common stock, resulting in approximately \$15.4 million of gross proceeds to Cellegy. Participants included current investors Baker/Tisch Investments and GMT Capital, as well as, five new investors.

In August 2001, Cellegy and Ventiv Integrated Solutions, a division of Ventiv Health, Inc., signed a six year agreement to commercialize Cellegy's lead product, Cellegesic, in the United States. Ventiv will deliver integrated marketing and sales solutions, will provide pre-launch support and will recruit and train a sales force that will be jointly managed by both companies. Ventiv will loan Cellegy up to \$10 million, the amount and timing depending on various circumstances, for expenses associated with the commercialization of Cellegesic under a funding agreement. Ventiv will also receive a share of product profitability through a multi-year royalty stream toward the end of the six-year agreement period.

In November 2001, we acquired a private Canadian based company, Vaxis Therapeutics, valued at \$4.1 million. The purchase was payable primarily in shares of Cellegy stock. The purchase price was allocated to net tangible assets of \$250,000, intangible assets of \$350,000 and \$3,507,000 million of in-process research and development. The intangibles of \$350,000 are being amortized over five years and the in-process research and development has been expensed in the fourth quarter of 2001. The acquired technology was in an early stage of development such that, as of the acquisition date, technological feasibility had not been reached and no alternative use exists. The assumptions used in determining the purchase price allocation were based on an appropriate discount rate applied to expected cash flows. The intangible assets will be amortized over 5 years.

The purchase agreement contains earn-out provisions for seven years that are based on commercial sales of any products developed by Cellegy based on technologies acquired from Vaxis. Any contingent consideration paid in the future will be accounted for as acquired in-process research and development. The results of operations of the acquired company have been included in the company's consolidated financial statements since the acquisition date. Accumulated amortization at December 31, 2001 is \$6,000. The expected amortization expense for the next five years will be approximately \$68,800 per year.

### **Critical Accounting Policies**

*Use of Estimates.* The preparation of consolidated financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Revenue Recognition.* Revenues related to cost reimbursement provisions under development contracts are recognized as the costs associated with the projects as these costs are incurred. Revenues related to milestones specified under development contracts are recognized as the milestones are achieved. Cellegy has received certain United States government grants that support our research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenues associated with these grants are recognized as costs under each grant as these costs are incurred. Revenues related to product sales are recognized upon shipment when title to the goods has been transferred to the customer. There is no right of return for our Rectogesic and skin care product sales.

*Clinical Trial Expenses.* Clinical trial expenses are payable to clinical sites and clinical research organizations. Expenses for both of these groups are accrued on a straight-line basis over the contracted period subject to adjustment for actual activity based on such factors as the number of subjects enrolled and number of subjects that have completed treatment for each trial. A monthly reconciliation of costs accrued to cost incurred is performed by Cellegy's clinical project managers and the finance department.

*Investment Policy.* Cellegy is subject to certain credit risk from our investment in marketable securities. By policy, we restrict amounts invested by investment type and by issuer, except for securities issued by the United States government. Cellegy has an investment policy that is approved and periodically reviewed by our Audit Committee. The policy states that investments must be highly liquid with maturities of less than three years. Cellegy's policy limits investments to the following: direct obligations of the United States Government or fully guaranteed by a government agency or by any of the states. Investments must have a rating of A1/P1 or A by Standard and Poors (or an equivalent rating); money market instruments must be a member of the Federal Reserve System with a net worth of at least \$100 million and a rating of A1/AA by Standard and Poors (or equivalent rating). Any exception to the above requires approval of the Chief Financial Officer and the Chief Executive Officer.

### **Results of Operations**

#### ***Years Ended December 31, 2001, 2000 and 1999***

*Revenues.* Cellegy had revenues of \$877,000, \$1,586,000, and \$1,045,000 in 2001, 2000 and 1999, respectively. Revenues in 2001 consisted of \$660,000 in product sales to Gryphon Development (Gryphon), the product development arm of a major specialty retailer, and \$217,000 in Rectogesic sales in Australia. Revenues in 2000 consisted of \$1,389,000 in product sales to Gryphon, \$125,000 in Rectogesic sales and \$72,000 in SBIR grant funding. The decrease of \$709,000 in total revenue in 2001 compared with 2000 was primarily due to a 52% or \$729,000 decrease in Gryphon sales which was partially due to an overstocking of inventory on Gryphon's part accompanied by a decline in economic conditions during the year. The SBIR grant funding of \$72,000 was completed in 2000. Revenues in 1999 consisted of \$898,000 in Gryphon sales, \$30,000 in SBIR grant funding and \$117,000 in development funding from Glaxo. The increase in total revenue in 2000 of \$541,000 or 52% compared with 1999 was primarily due to a \$491,000 increase in Gryphon sales and \$125,000 in Rectogesic sales partially offset by higher grant funding of \$75,000 in 1999.

*Research and Development Expenses.* Research and development expenses were \$14,098,000 in 2001 compared with \$9,574,000 in 2000, and \$7,965,000 in 1999. Total research and development expenses represented 65%, 70% and 73% of our total operating expenses in 2001, 2000 and 1999, respectively. Total expenses in 2001 compared to 2000 increased by \$4,524,000. Approximately 81% or \$3,632,000 of the increase was due to expenses associated with the completion of the Cellegesic Phase III study, NDA filing fees, costs related to the Phase II clinical studies relating to hemorrhoids, as well as costs associated with Tostrex and Tostrelle clinical studies. The remaining 18% or \$830,000 was due to non-cash expenses related to milestone payments made to Neptune Pharmaceuticals and non-cash compensation charges related to stock options. Future potential milestones payable in Cellegy common stock to Neptune on the achievement of Cellegesic development milestones could result in future non-cash research and development expenses of up to \$9 million. The increase of \$1,609,000 or 16% in 2000 compared with 1999 was primarily due to an increase in spending associated with Cellegesic Phase III and Phase II clinical trials, as well as Phase III and Phase I/II Tostrex and Tostrelle clinical studies, respectively. Research and development expenses include salaries and benefits, laboratory supplies, external research programs, clinical studies and allocated overhead costs such as rent, supplies and utilities. In addition to clinical site payments, clinical costs include costs of manufacturing clinical supplies and costs associated with product stability studies.

We expect our research and development expenses in 2002 to be equal to or higher than 2001 levels, primarily due to our Phase II/III Tostrelle study, the planned NDA filing for Tostrex, two hemorrhoid trials using Cellegesic and in support of on-going research in Cellegy Canada. Unexpected increases in research and development expenses may occur if the FDA requires further trials to support our NDA filing for Cellegesic and Tostrex. However, in case of a delay in the approval of the Cellegesic NDA, Cellegy may need to reduce or defer overall expenditures, particularly in marketing and sales.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$4,042,000 in 2001, compared with \$3,631,000 in 2000 and \$2,613,000 in 1999. The increase of \$411,000 or 11% in 2001 compared with 2000 was mostly due to expenses associated with our business development programs and a substantial increase in utility expenses and consulting fees. The increase in expenses of \$1,018,000 in 2000 compared with 1999 was primarily due to non-cash compensation charges related to certain warrant grants. Our general and administrative expenses are expected to continue to increase in the future in support of our business development programs and product commercialization efforts.

*Acquired-In-Process Research and Development.* Acquired-in-process research and development expenses of \$3,507,000 were incurred during 2001 as a result of the Vaxis acquisition. There were no acquired-in-process research and development expenses incurred during 2000 and 1999. The acquired technology was at an early stage of development such that, at the acquisition date, technological feasibility had not been reached and no alternative use existed.

*Interest Income, and Other Net and Interest Expense.* Cellegy recognized \$1,532,000 in interest income for 2001 compared with \$770,000 for 2000 and \$864,000 for 1999. Fluctuations in interest income were tied primarily to changes in the average investment balances during each year. Interest expenses were \$27,000 in 2001 compared with \$201,000 in 2000 and \$363,000 in 1999. Interest expenses in 2001 were lower due to a bank loan that was repaid in 2001. Other income includes rental income from our sub-lessees of \$896,000 in 2001 compared with \$80,000 in 2000. Cellegy's sub-lease agreement expired in December 2001, and this may result in significant decrease in rental income if favorable sub-leases are not found this year.

*Net Loss.* The net loss applicable to common shareholders in 2001 was \$19,465,000 or \$1.26 per share based on 15,503,000 weighted average shares outstanding compared with the net loss applicable to common shareholders in 2000 of \$11,418,000 or \$0.91 per share based on 12,542,000 weighted average shares outstanding. In 1999, our net loss was \$9,301,000 or \$0.85 per share based on 10,914,000 weighted average shares outstanding.

#### **Liquidity and Capital Resources**

We have experienced net losses and negative cash flows from operations each year since our inception. Through December 31, 2001, we had incurred an accumulated deficit of \$70.4 million and had

consumed cash from operations of \$54.7 million. Cash from equity financing transactions have included \$6.4 million in net proceeds from our initial public offering in August 1995, \$6.8 million in net proceeds from a preferred stock financing in April 1996, \$3.8 million in net proceeds from a private placement of common stock in July 1997, \$13.8 million in net proceeds from a follow-on public offering in November 1997, \$10.0 million in net proceeds from a private placement in July 1999, \$11.6 million in net proceeds from a private placement in October 2000 and \$15.1 million in net proceeds from a private placement in June 2001. In June 1998, we entered into a loan agreement with a commercial bank to provide up to \$4.5 million with an initial interest rate at the bank's prime lending rate plus 0.75%. In December 1999, the loan was amended to include a revolving credit line allowing us to pay down principal balances at any time or increase borrowings up to a maximum of \$2.5 million. As of December 31, 2001, there was no loan balance outstanding under this arrangement.

Our cash and investments were \$17.2 million at December 31, 2001 compared with \$15.9 million at December 31, 2000, both of which includes \$614,000 of restricted cash. At December 31, 1999, cash and investments were \$16.7 million. The increase in cash and investments of \$1.3 million in 2001 was principally due to the net proceeds from the financing completed in June 2001, partially offset by net cash used in operating activities of \$13.0 million. Our operations have used and will continue to use substantial amounts of cash. Future expenditures and capital requirements depend on numerous factors including, without limitation, the progress and focus of our research and development programs, the progress and results of pre-clinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, our ability to establish new collaborative arrangements, the initiation of commercialization activities, the purchase of capital equipment, and the availability of other financing.

We have a ten-year operating lease commitment on our facility with our current landlord. Our operating lease commitments are \$1,488,000 for 2002 and \$12,280,000 thereafter.

In order to complete the research and development and other activities necessary to commercialize our products, additional financing will be required. As a result, we will seek private or public equity investments and future collaborative arrangements or other transactions with third parties to meet such needs. There is no assurance that financing will be available for us to fund our operations on acceptable terms, if at all. Insufficient funding may require us to delay, reduce or eliminate some or all of our research and development activities, planned clinical trials, marketing, sales, product promotion and administrative programs. We believe that available cash resources and the interest thereon, together with funding under the Ventiv agreements, will be adequate to satisfy our capital needs through at least December 31, 2002, although failure to obtain additional financing could require us to delay or reduce the scope of some of our planned research, development and sales and marketing activities.

We have paid fees to the Company's board members for their services on the board, audit committee and compensation committee. The total fees paid to these directors during 2001, 2000 and 1999 were \$57,750, \$46,500 and \$30,000.

Additional consulting fees were paid to two board members based on consulting agreements. These were \$80,000 and \$66,000 for 2001 and 2000, respectively.

We have also recognized \$100,888 in non-cash compensation expense during 2001 for a consulting agreement with a current board member. The Company issued stock options to this board member for his consulting services.

### **Recent Accounting Pronouncements**

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 141, "Business Combinations" (Statement 141). This Statement addresses financial accounting and reporting for business combinations. Statement 141 supersedes APB Opinion No. 16, Business Combinations (Opinion 16), and amends or supersedes a number of interpretations of that Opinion.

Statement 141 requires that (1) all business combinations be accounted for by a single method - the purchase method, (2) all intangible assets acquired in a business combination are to be recognized as

assets apart from goodwill if they meet one of two criteria - the contractual-legal criterion or the separability criterion and (3) in addition to the disclosure requirements in Opinion 16, disclosure of the primary reasons for a business combination and the allocation of the purchase price paid to the assets acquired and liabilities assumed by major balance sheet caption. When the amounts of goodwill and intangible assets acquired are significant in relation to the purchase price paid, disclosure of other information about those assets is required, such as the amount of goodwill by reportable segment and the amount of the purchase price assigned to each major intangible asset class. The provisions of Statement 141 apply to all business combinations initiated after June 30, 2001. Cellegy adopted the provisions of Statement 141 as of July 1, 2001.

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangibles" (Statement 142). Under Statement 142, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Separable intangible assets that are not deemed to have an indefinite life will continue to be amortized over their estimated useful lives. Prior to December 31, 2001, Cellegy had recorded goodwill of \$968,000 related to the Quay acquisition in June 2000. Cellegy will discontinue amortizing the remaining balance in goodwill of \$814,000 on January 1, 2002. The adoption of this statement as of January 1, 2002 is not expected to have any other impact on our financial position, results of operations or cash flows.

In October 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" (Statement 144), which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. Statement 144 is effective for Cellegy's fiscal year beginning January 2002. Cellegy does not expect that the adoption of the Statement will have a significant impact on our financial position and results of operations.

#### **Factors That May Affect Future Operating Results**

This report contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in this Annual Report. Factors that might cause such a difference include, but are not limited to, those discussed below.

#### ***We are subject to regulation by regulatory authorities including the FDA, which could delay or prevent marketing of our products.***

Cellegy's prescription product candidates, and our ongoing research and clinical activities such as those relating to our product candidates Cellegesic, Tostrex, and Tostrelle, are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. Extensive current pre-clinical and clinical testing requirements and the regulatory approval process of the United States Food and Drug Administration (FDA) in the United States and of certain foreign regulatory authorities, or additional future government regulations, could prevent or delay regulatory approval of Cellegy's products. Disagreements may occur in the future, and one or more of our ongoing or planned clinical trials could be delayed or be required to be repeated in order to satisfy regulatory requirements. The FDA could impose requirements on future trials that could delay or prevent the regulatory approval process for Cellegesic, Tostrex or Tostrelle. Sales of Cellegy's products outside the United States are subject to regulatory requirements governing clinical trials and marketing approval. These requirements vary widely from country to country and could delay introduction of Cellegy's products in those countries.

Before we obtain regulatory approval for the commercial sale of most potential drug products, we must demonstrate through pre-clinical studies and clinical trials that the product is safe and efficacious for use in the clinical indication for which approval is sought. We cannot assure you that the FDA or other international regulatory authorities will permit us to undertake any future clinical trials for potential products or to continue any of the current clinical trials. To date, except for our NDA filing in June 2001 relating to Cellegesic, we have not sought FDA approval to distribute any products. Moreover, results of pre-clinical studies and early clinical trials may not be good predictors of results that will be obtained in later-stage clinical trials and favorable results in later stage clinical trials may not ensure FDA approval to commercialize a product. We cannot assure you that Cellegy's present or future clinical trials will

demonstrate the results required for approval to market these potential products or even to continue with additional clinical development. Because of the independent and blind nature of certain human clinical testing, there will be extended periods during the testing process when we will have only limited, or no, access to information about the status or results of the tests. Other pharmaceutical companies have believed that their products performed satisfactorily in early tests, only to find their performance in later tests, including Phase III clinical trials, to be inadequate or unsatisfactory, or that FDA Advisory Committees have declined to recommend approval of the drugs, or that the FDA itself refused approval, with the result that such companies' stock prices have fallen precipitously.

The timing of NDA submissions, the outcome of reviews by the FDA and the initiation and completion of other clinical trials are subject to uncertainty, change and unforeseen delays. On December 3, 2001, Cellegy announced that it had submitted an amendment to its NDA for Cellegesic to include data from a recently completed confirmatory Phase III clinical study using Cellegesic to treat pain associated with chronic anal fissures. The Cellegesic NDA was originally filed in June 2001. There can be no assurance, however, that the FDA will find the Cellegesic trial data, the statistical analysis methodology used by Cellegy, or other sections of the NDA acceptable for marketing approval. The FDA could require further trials, decide to have an Advisory Panel review the submission, with an uncertain outcome of such panel's recommendation, or take other actions having the effect of delaying or preventing commercial introduction of Cellegesic. In addition, having submitted the Cellegesic NDA in June 2001 before completion of the second Phase III trial does not necessarily reduce the period of time during which the FDA reviews the filing and may have no effect on the regulatory review period; the FDA could decide, among other things, to re-start its review as of November 2001, when Cellegy submitted an amendment to the NDA. Any delay in obtaining regulatory approval for Cellegesic could have a material adverse effect on the market price of the Common Stock and our business.

***We have a history of losses, and we expect losses to continue for at least several years.***

Our accumulated deficit as of December 31, 2001 was approximately \$70.4 million. We have never operated profitably and, given our planned level of operating expenses, we expect to continue to incur losses for at least the next two years. We plan to increase our operating expenses as we continue to devote significant resources to pre-clinical studies, clinical trials, administrative, marketing, sales and patent activities. Accordingly, without substantial revenues from new corporate collaborations, royalties on product sales or other revenue sources, we expect to incur substantial operating losses in the foreseeable future as our potential products move into commercialization, and we continue to invest in research and clinical trials. Our losses may increase in the future, and even if we achieve our revenue targets, we may not be able to sustain or increase profitability on a quarterly or annual basis. The amount of future net losses, and the time required to reach profitability, are both highly uncertain. To achieve sustained profitable operations, we must, among other things, successfully discover, develop, obtain regulatory approvals for and market pharmaceutical products. We cannot assure you that we will ever be able to achieve or sustain profitability.

***The Company faces intense competition from larger companies, and in the future Cellegy may not have the resources required to develop innovative products. Cellegy's products are subject to competition from existing products.***

The pharmaceutical and cosmeceutical industries are subject to rapid and significant technological changes. In the development and marketing of topical prescription drugs, skin care and other products and drug delivery systems, Cellegy faces intense competition. Cellegy is much smaller in terms of size and resources than many of its competitors in the United States and abroad, which include, among others, major pharmaceutical, chemical, cosmetic, consumer product and biotechnology companies, specialized firms, universities and other research institutions. Cellegy's competitors may succeed in developing technologies and products that are more effective than any that we are developing and could render Cellegy's technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, clinical, production and marketing capabilities and regulatory experience. In addition, Cellegy's products are subject to competition from existing products.

For example, Cellegy's Tostrex product, if commercialized, is expected to compete with two currently marketed transdermal patch products sold by Johnson and Johnson and Watson Pharmaceuticals and one transdermal testosterone gel product marketed by Unimed/Solvay. Cellegy's Cellegesic product, if commercialized, is expected to compete with over-the-counter products, such as Preparation H marketed by American Home Products, and various other prescription products. As a result, we cannot assure you that Cellegy's products under development will be able to compete successfully with existing products or innovative products under development by other organizations.

***Our prospects for obtaining additional financing, if required, are uncertain and failure to obtain needed financing could affect our ability to develop or market products.***

Throughout our history, we have consumed substantial amounts of cash. Our cash needs are expected to continue to increase significantly over at least the next two years in order to fund the additional expenses required to expand our current research and development programs and to commercialize our products once regulatory approvals have been obtained. Cellegy has no current source of significant ongoing revenues or capital beyond existing cash and investments, and certain product sales of Rectogesic in Australia and sales to Gryphon, the development subsidiary of a major specialty retailer. In order to complete the research and development and other activities necessary to commercialize our products, additional financing will be required.

Cellegy will seek private or public equity investments and future collaborative arrangements with third parties to help fund future cash needs. Such funding may not be available on acceptable terms, if at all. Cellegy believes that available cash resources and interest earned, together with funding under the Ventiv agreements, will be adequate to satisfy its capital needs through at least December 31, 2002, although failure to obtain additional financing could require us to delay or reduce the scope of some of our planned research, development and sales and marketing activities.

***Our stock price could be volatile.***

Our stock price has from time to time experienced significant price and volume fluctuations. Sometimes our stock price has varied depending on fluctuations in the Nasdaq National Market generally, and sometimes fluctuations have resulted from matters more specific to Cellegy, such as an announcement of clinical trial or regulatory results or other corporate developments. Announcements that could significantly impact our stock price include:

- clinical trial results, such as results of Cellegesic, Tostrex or Tostrelle trials;
- developments or disputes concerning patent or proprietary rights;
- publicity or announcements regarding regulatory developments relating to our products under review or by our competitors;
- period-to-period fluctuations in our financial results, including operating expenses or profits, and
- negative announcements by our key suppliers or service providers.

***The type and scope of patent coverage we have may limit the commercial success of our products.***

Cellegy's success depends, in part, on our ability to obtain patent protection for our products and methods, both in the United States and in other countries. Several of Cellegy's products are based on existing compounds with a history of use in humans but are being developed by Cellegy for new therapeutic uses. Cellegy cannot obtain composition patent claims on the compound itself, and will instead need to rely on patent claims, if any, directed to use of the compound to treat certain conditions or to specific formulations we are attempting to develop. Cellegy may not be able to prevent a competitor from using our formulations or compounds for a different purpose. Certain United States and foreign patents have previously been issued to Cellegy. However, we cannot assure you that any additional patents will be issued to Cellegy, that the protection of any patents issued in the future will be commercially valuable or that current or future patents will be held valid if subsequently challenged.

The patent position of companies engaged in businesses such as Cellegy's business generally is uncertain and involves complex legal and factual questions. There is a substantial backlog of patent



applications at the United States Patent and Trademark Office. Further, issued patents can later be held invalid by the patent office issuing the patent or by a court. There can be no assurance that any patent applications relating to Cellegy's products or methods will issue as patents, or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us a competitive advantage. For example, we reported in July 2001 that two oppositions had been filed with the European Patent Office regarding our European patent protecting the manufacture and use of nitroglycerin ointment and related compounds for the treatment of anal disorders, including fissures and various hemorrhoidal conditions. An adverse outcome in either opposition proceeding could have a material adverse effect on Cellegy, including marketing efforts in Europe. In addition, many other organizations are engaged in research and product development efforts in drug delivery, skin biology and cosmeceutical fields that may overlap with Cellegy's products. Such organizations may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by Cellegy. These rights may prevent us from commercializing technology, or may require Cellegy to obtain a license from the organizations to use the technology. Cellegy may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, or that the patents underlying any such licenses will be valid or enforceable. Moreover, the laws of certain foreign countries do not protect intellectual property rights relating to United States patents as extensively as those rights are protected in the United States. Cellegy is subject to the risk that individuals or organizations located in such countries will engage in development, marketing or sales activities of Cellegy's products.

***Our product sales strategy involving corporate partners is highly uncertain.***

Cellegy is seeking to enter into agreements with certain corporate partners granting rights to commercialize our lead product candidates, Cellegesic and Tostrex. Other than the agreement with Ventiv, Cellegy has not entered into any agreements with third parties to commercialize either product candidate. Cellegy may not be able to establish any such collaborative arrangements and we may not have the resources or the experience to successfully commercialize any such products on our own. Failure to enter into any such arrangements could prevent, delay or otherwise have a material adverse effect on our ability to develop and market Cellegesic, Tostrex or other products (particularly in certain international markets) that we desire to commercialize through third party arrangements. Similarly, if we are unable to find another corporate partner to develop or market our cosmeceutical products, they may never be commercialized. If we are able to enter into one or more corporate partner arrangements, we may rely on our partners to conduct clinical trials, obtain regulatory approvals and, if approved, manufacture, distribute and market or co-promote these products.

However, reliance on third party partners can create risks to our product commercialization efforts. Once agreements are completed, Cellegy may have little or no control over the development of these potential products and little or no opportunity to review clinical data before or after public announcement of results. Further, any arrangements that may be established may not be successful.

For example, Cellegy and Ventiv finalized a six-year services agreement and a related funding agreement to commercialize our lead product, Cellegesic. There is no guarantee that Ventiv will be able to successfully complete its funding or other obligations to Cellegy. Non-performance by Ventiv could delay the commercial introduction of Cellegesic and delay sales of Cellegesic. Cellegy may need to seek alternative arrangements for the commercialization of the product which could have a material adverse effect on our business and our ability to commercialize Cellegesic in a timely manner.

***No History of Manufacturing Products; Limited Number of Critical Suppliers.***

Cellegy has no direct experience in manufacturing commercial quantities of products and currently does not have any capacity to manufacture products on a large commercial scale. We currently rely on a limited number of contract manufacturers, primarily PanGeo, and suppliers to manufacture our formulations. Although we believe that there will be adequate third party manufacturers, there can be no assurance that we will be able to enter into acceptable agreements with them. In the future, we may not be able to obtain contract manufacturing on commercially acceptable terms for compounds or product

formulations in the quantities we need. Manufacturing or quality control problems could occur at the contract manufacturers causing product shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's current good manufacturing practice requirements necessary to continue manufacturing our products.

**ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Cellegy invests its excess cash in short-term, investment grade, fixed income securities under an investment policy. All of our investments are classified as available-for-sale (see Financial Statements - Note 2). Approximately 25% of our securities will mature in 2002, 35% will mature in 2003 with the remainder in money market funds. We believe that potential near-term losses in future earnings, fair values or cash flows related to our investment portfolio are not significant.

At December 31, 2001, our investment portfolio consisted of \$6,758,000 in corporate notes, \$2,022,000 in government securities and \$2,000,000 in commercial paper. We currently do not hedge interest rate exposure. If market interest rates were to increase by 100 basis points or 1% from December 2001 levels, the fair value of our portfolio would decline by no more than \$50,000. The modeling technique used measures the change in fair value from a hypothetical shift in market interest rates.

**ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements required by item 8 are set forth below on pages F-1 through F-22 of this report.

**ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES.**

None.

### **PART III**

#### **ITEM 10: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

Information required by this Item with respect to directors and compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the sections captioned "Election of Cellegy Directors" and "Compliance under Section 16(a) of the Securities Exchange Act of 1934" appearing in the definitive Proxy Statement (the "2002 Proxy Statement") to be delivered to shareholders in connection with the Annual Meeting of Shareholders expected to be held on June 5, 2002. Such information is incorporated herein by reference. Information required by this Item with respect to executive officers may be found in Part I hereof in the section captioned "Executive Officers of the Registrant."

#### **ITEM 11: EXECUTIVE COMPENSATION**

Information with respect to this Item may be found in the section captioned "Executive Compensation" appearing in the 2002 Proxy Statement and is incorporated herein by reference.

#### **ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

Information with respect to this Item may be found in the section captioned "Security Ownership of Certain Beneficial Owners and Management" appearing in the 2002 Proxy Statement and is incorporated herein by reference.

#### **ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Information with respect to this Item may be found in the section captioned "Certain Relationships and Related Transactions" appearing in the 2002 Proxy Statement and is incorporated herein by reference.

## PART IV

### ITEM 14: EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

#### Exhibits

(a) The following exhibits are attached hereto or incorporated herein by reference:

<u>Exhibit Number</u>	<u>Exhibit Title</u>
2.1	Asset Purchase Agreement dated December 31, 1997 between the Company and Neptune Pharmaceutical Corporation. (Confidential treatment has been granted with respect to portions of this agreement.) (Incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-3 file no. 333-46087 on February 11, 1998.
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Registration No. 33-93288 LA) declared effective on August 11, 1995 (the "SB-2").)
3.2	Bylaws of the Company. (Incorporated by reference to Exhibit 3.3 to the SB-2.)
4.1	Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.1 to the SB-2.)
10.1	License Agreement, dated March 4, 1994, regarding Drug Delivery by Skin Barrier Disruption, between the Company and University of California. (Incorporated by reference to Exhibit 10.6 to the SB-2.)
*10.2	1992 Stock Option Plan. (Incorporated by reference to Exhibit 10.12 to the SB-2.)
10.5	Warrant Agreement dated as of February 10, 1995. (Incorporated by reference to Exhibit 10.15 to the SB-2.)
10.6	Agency Agreement dated as of February 10, 1995. (Incorporated by reference to Exhibit 10.16 to the SB-2.)
*10.7	1995 Equity Incentive Plan (Incorporated by reference to Exhibit 10.17 to the Annual Report on Form 10-KSB for the year ended December 31, 1995, the "1995 Form 10-KSB".)
*10.8	1995 Directors' Stock Option Plan (Incorporated by reference to Exhibit 10.18 to the 1995 Form 10-KSB.)
10.9	Loan and Security Agreement between Silicon Valley Bank and the Company dated June 10, 1998 (Incorporated by reference to Exhibit 10.01 to the Company's Form 10-QSB for the fiscal quarter ended June 30, 1998.)
10.10	Lease Agreement between the Company and TCNorthern California Inc. dated April 8, 1998 (Incorporated by reference to Exhibit 10.01 to the Company's Form 10-QSB for fiscal quarter ended March 31, 1998.)
*10.11	Employment Agreement dated November 20, 1996, between the Company and K. Michael Forrest. (Incorporated by reference to Exhibit 10.19 to the Company's Form 10-KSB for fiscal year ended December 31, 1996 (the "1996 Form 10-KSB".)
10.12	Services Agreement dated as of August 10, 2001 by and among the Company, Ventiv Health Inc. and VIS Financial LLC. (Confidential treatment has been requested with respect to portions of this agreement.)
10.13	Funding Arrangement dated August 10, 2001 by and among the Company, Ventiv Health Inc. and VIS Financial LLC. (Confidential treatment has been requested with respect to portions of this agreement.)
10.14	Share Purchase Agreement dated as of November 27, 2001, by and among the Company, Vaxis Therapeutics Corporation and certain stockholders of Vaxis.

<u>Exhibit Number</u>	<u>Exhibit Title</u>
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney (See signature page.)
27.1	Financial Data Schedule.

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\* Represents a management contract or compensatory plan or arrangement.

(b) Reports on Form 8-K

One report on Form 8-K was filed by Cellegy on January 3, 2002 announcing our acquisition of Vaxis Therapeutics and our submission of the NDA supplement with the FDA in December 2001.

(c) Financial Statement Schedules

All schedules are omitted because they are not applicable or are not required, or the information required to be set forth therein is included in the financial statements or notes thereto.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South San Francisco, State of California, on the 12th of March, 2002.

CELLEGY PHARMACEUTICALS, INC.

A handwritten signature in black ink, appearing to read "K. Michael Forrest". The signature is stylized with a large initial "K" and a cursive "Forrest".

K. Michael Forrest  
Chairman, President and Chief Executive Officer

### Power of Attorney

Each person whose signature appears below constitutes and appoints each of K. Michael Forrest and A. Richard Juelis, true and lawful attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and conforming all that said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<b>Principal Executive Officer:</b>		
<u>/s/ K. Michael Forrest</u> K. Michael Forrest	Chairman, President, Chief Executive Officer and Director	March 12, 2002
<b>Principal Financial Officer and Principal Accounting Officer:</b>		
<u>/s/ A. Richard Juelis</u> A. Richard Juelis	Vice President, Finance, Chief Financial Officer and Secretary	March 12, 2002
<b>Directors:</b>		
<u>/s/ Carl R. Thornfeldt</u> Carl R. Thornfeldt, M.D.	Director	March 12, 2002
<u>/s/ Jack L. Bowman</u> Jack L. Bowman	Director	March 12, 2002
<u>/s/ Felix J. Baker</u> Felix J. Baker, Ph.D.	Director	March 12, 2002
<u>/s/ Julian C. Baker</u> Julian C. Baker	Director	March 12, 2002
<u>/s/ Tobi B. Klar</u> Tobi B. Klar, M.D.	Director	March 12, 2002
<u>/s/ Ronald J. Saldarini</u> Ronald J. Saldarini, Ph.D.	Director	March 12, 2002
<u>/s/ Alan A. Steigrod</u> Alan A. Steigrod	Director	March 12, 2002
<u>/s/ Larry J. Wells</u> Larry J. Wells	Director	March 12, 2002

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## **Report of Ernst & Young LLP, Independent Auditors**

The Board of Directors and Shareholders  
Cellegy Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Cellegy Pharmaceuticals, Inc. (a development stage company) as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2001, and for the period from June 26, 1989 (inception) through December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cellegy Pharmaceuticals, Inc. and subsidiaries (a development stage company) at December 31, 2001 and 2000 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, and for the period from June 26, 1989 (inception) to December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Palo Alto, California  
February 7, 2002

**Cellegy Pharmaceuticals, Inc.**  
(a development stage company)

**Consolidated Statement of Shareholders' Equity (Continued)**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of convertible preferred stock, net of issuance cost through December 31, 1998 . . . . .	27,649	\$ 6,801,730	—	\$ —	477,081	\$ 4,978,505	—	\$ —	\$ —	—	\$11,780,235
Issuance of Series A convertible preferred stock and warrants to purchase 14,191 shares of Series A convertible preferred stock in exchange for convertible promissory notes and accrued interest through December 31, 1998 . . . . .	625,845	1,199,536	—	—	—	—	—	—	—	—	1,199,536
Issuance of convertible preferred stock for services rendered, and license agreement through December 31, 1998 . . . . .	50,110	173,198	—	—	—	—	—	—	—	—	173,198
Issuance of Series B convertible preferred stock in exchange for convertible promissory note . . . . .	—	—	12,750	114,000	—	—	—	—	—	—	114,000
Non-cash preferred dividends . . . . .	—	1,448,505	—	—	—	—	—	—	—	(1,448,505)	—
Conversion of preferred stock, including dividends, to common stock through December 31, 1998 . . . . .	(703,604)	(9,622,969)	(12,750)	(114,000)	(477,081)	(4,978,505)	3,014,644	14,715,474	—	—	—
Issuance of warrants in connection with notes payable in financing . . . . .	—	—	—	—	—	—	—	487,333	—	—	487,333
Issuance of common stock in connection with private placement of common stock in July 1997, net of issuance cost . . . . .	—	—	—	—	—	—	1,547,827	3,814,741	—	—	3,814,741
Issuance of common stock in connection with the public offering of common stock in November 1997, net of issuance cost . . . . .	—	—	—	—	—	—	2,012,500	13,764,069	—	—	13,764,069
Issuance of common stock in connection with the acquisition of Neptune Pharmaceutical . . . . .	—	—	—	—	—	—	462,809	3,842,968	—	—	3,842,968

See accompanying notes.

**Cellegy Pharmaceuticals, Inc.**  
(a development stage company)

**Consolidated Statement of Shareholders' Equity (Continued)**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of common stock in connection with IPO in August 1995 . . . . .	—	—	—	—	—	—	1,322,500	6,383,785	—	—	6,383,785
Issuance of common stock for cash through December 31, 1998 . . . . .	—	—	—	—	—	—	953,400	126,499	—	—	126,499
Issuance of common stock for services rendered through December 31, 1998 . . . . .	—	—	—	—	—	—	269,116	24,261	—	—	24,261
Repurchase of common shares in 1992 . . . . .	—	—	—	—	—	—	(3,586)	(324)	—	—	(324)
Issuance of common stock in exchange for notes payable . . . . .	—	—	—	—	—	—	42,960	268,500	—	—	268,500
Exercise of warrants to purchase common stock . . . . .	—	—	—	—	—	—	377,082	100,484	—	—	100,484
Exercise of options to purchase common stock . . . . .	—	—	—	—	—	—	174,045	496,862	—	—	496,862
Compensation expense related to the extension of option exercise periods . . . . .	—	—	—	—	—	—	—	338,481	—	—	338,481
Unrealized gain on investments . . . . .	—	—	—	—	—	—	—	—	47,353	—	47,353
Net loss for the period June 26, 1989 (inception) to December 31, 1998 . . . . .	—	—	—	—	—	—	—	—	—	(28,743,951)	(28,743,951)
Balances at December 31, 1998 . . . . .	—	—	—	—	—	—	10,173,294	44,363,133	47,353	(30,192,456)	(14,218,030)
Issuance of common stock in connection with the private placement of common stock in July 1999 net of issuance cost . . . . .	—	—	—	—	—	—	1,616,000	10,037,662	—	—	10,037,662
Exercise of warrants to purchase common stock . . . . .	—	—	—	—	—	—	119,171	502,195	—	—	502,195
Exercise of options to purchase common stock . . . . .	—	—	—	—	—	—	101,777	464,913	—	—	464,913
Unrealized loss on investments . . . . .	—	—	—	—	—	—	—	—	(82,824)	—	(82,824)
Net loss . . . . .	—	—	—	—	—	—	—	—	—	(9,301,156)	(9,301,156)
Total Comprehensive Loss . . . . .	—	—	—	—	—	—	—	—	—	—	(9,383,980)

See accompanying notes.

**Cellegy Pharmaceuticals, Inc.**  
(a development stage company)

**Consolidated Statement of Shareholders' Equity (Continued)**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at December 31, 1999 . . .	—	—	—	—	—	—	12,010,242	55,367,903	(35,471)	(39,493,612)	15,838,820
Issuances of common stock in connection with the private placement of common stock in October 2000, net of issuance costs of \$22,527 . . . . .	—	—	—	—	—	—	1,500,000	11,602,473	—	—	11,602,473
Exercise of warrants to purchase common stock . . . . .	—	—	—	—	—	—	62,833	315,800	—	—	315,800
Exercise of options to purchase common stock . . . . .	—	—	—	—	—	—	95,754	380,516	—	—	380,516
Fair value of warrants issued in Quay acquisition . . . . .	—	—	—	—	—	—	—	489,477	—	—	489,477
Common stock issued in connection with Quay acquisition . . . . .	—	—	—	—	—	—	169,224	977,105	—	—	977,105
Compensation expense related to warrants and options granted to non-employees . . . . .	—	—	—	—	—	—	—	601,748	—	—	601,748
Unrealized gain on investments . . . . .	—	—	—	—	—	—	—	—	8,201	—	8,201
Foreign currency translation . . . . .	—	—	—	—	—	—	—	—	(1,537)	—	(1,537)
Net loss . . . . .	—	—	—	—	—	—	—	—	—	(11,418,213)	(11,418,213)
Total Comprehensive Loss . . . . .	—	—	—	—	—	—	—	—	—	(11,418,213)	(11,418,213)
Balances at December 31, 2000 . . .	—	—	—	—	—	—	13,838,053	69,735,022	(28,807)	(50,911,825)	18,794,390
Issuance of common stock in connection with the private placement of common stock in June 2001, net of issuance costs of \$184,795 . . . . .	—	—	—	—	—	—	2,747,143	15,199,206	—	—	15,199,206
Exercise of warrants to purchase common stock . . . . .	—	—	—	—	—	—	12,000	48,000	—	—	48,000
Exercise of options to purchase common stock . . . . .	—	—	—	—	—	—	60,803	203,437	—	—	203,437
Common stock issued in connection with Vaxis acquisition . . . . .	—	—	—	—	—	—	533,612	3,852,630	—	—	3,852,630
Compensation expense related to warrants and options granted to non-employees . . . . .	—	—	—	—	—	—	—	349,516	—	—	349,516

See accompanying notes.

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**  
**Consolidated Statements of Cash Flows (Continued)**

	Years ended December 31,			Period from June 26, 1989 (inception) to December 31, 2001
	<u>2001</u>	<u>2000</u>	<u>1999</u>	
<b>Supplemental cash flow information</b>				
Interest paid .....	<u>\$ 27,281</u>	<u>\$ 200,689</u>	<u>\$362,735</u>	<u>\$ 612,851</u>
<b>Supplemental disclosure of non-cash transactions:</b>				
Issuance of common stock and warrants in connection with acquisitions .....	<u>\$3,986,071</u>	<u>\$1,466,000</u>	<u>\$ —</u>	<u>\$ 9,295,039</u>
Conversion of preferred stock to common stock .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$14,715,474</u>
Issuance of common stock for notes payable .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 277,250</u>
Issuance of warrants in connection with notes payable financing .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 487,333</u>
Issuance of convertible preferred stock for notes payable .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,268,316</u>
Issuance of common stock for Neptune milestone payments .....	<u>\$ 750,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 750,000</u>

See accompanying notes.

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements**

**1. Accounting Policies**

*Description of Business and Principles of Consolidation*

The consolidated financial statements include the accounts of Cellegy Pharmaceuticals, Inc. and its subsidiaries (the "Company"). All significant inter-company balances and transactions have been eliminated in consolidation.

The Company was incorporated in California in June 1989 and is a development stage company. Since its inception, the Company has engaged primarily in research and clinical development activities associated with its current and potential future products and its transdermal drug delivery and topical formulation expertise. The Company has conducted a number of clinical trials using its products, including the preparation of manufactured clinical materials. A number of sponsored, external research programs have been undertaken.

*Use of Estimates*

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Revenue Recognition and Research and Development Expenses*

Revenues related to cost reimbursement provisions under development contracts are recognized as the costs associated with the projects are incurred. Revenues related to milestones specified under development contracts are recognized as the milestones are achieved. The Company receives certain United States government grants that support the Company's research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenues associated with these grants are recognized as costs under each grant are incurred. Revenues related to product sales are recognized upon shipment when title to goods has been transferred to the customer. There is no right of return for product sales. Receivables are collected within thirty days of shipment.

Research and development costs are expensed as incurred. The type of costs included in research and development expenses include salaries and benefits, laboratory supplies, external research programs, clinical studies and allocated costs such as rent, supplies and utilities.

Clinical trial expenses are payable to clinical sites and clinical research organizations. Expenses for both of these groups are accrued on a straight-line basis over the contracted period subject to adjustment for actual activity based on such factors as the number of subjects enrolled and number of subjects that have completed treatment for each trial. A monthly reconciliation of costs accrued to cost incurred is performed by Cellegy's clinical project managers and the finance department.

*Cash, Cash Equivalents and Investments*

Cash equivalents consist of highly liquid financial instruments with original maturities of three months or less. The carrying value of cash and cash equivalents approximates fair value at December 31, 2001 and 2000. The Company considers all its investments as available-for-sale and reports these investments at estimated fair market value using available market information. Unrealized gains or losses on available-for-sale securities are included in shareholders' equity as other comprehensive income (loss) until their disposition. The cost of securities sold is based on the specific identification method. Realized gains or losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest income and other, net.

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

The Company is subject to credit risk from its portfolio of marketable securities. By policy, the Company restricts amounts invested in such securities by investment type and by issuer except for securities issued by the U.S. government.

*Property and Equipment*

Property and equipment are stated at cost less accumulated depreciation. Furniture and fixtures, and office and laboratory equipment are depreciated using the straight-line method over estimated useful lives ranging from three to five years. Amortization for leasehold improvements is taken over the shorter of the estimated useful life of the asset or the remaining lease term.

*Goodwill*

Goodwill that is related to the purchase of Quay Pharmaceuticals in June 2000, included in intangible assets, represents the excess purchase price over the fair value of net assets acquired which was being amortized over 10 years using the straight-line method. The carrying value of goodwill is based on management's current assessment of recoverability using objective and subjective factors.

Amortization taken to date as of December 31, 2001 was approximately \$652,000. Effective January 1, 2002, the Company will no longer amortize the remaining balance of goodwill of \$814,400 but will assess goodwill, at least annually, for impairment. (see New Accounting Standards below).

*Stock-Based Compensation*

The Company accounts for its stock option grants in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB25") and related Interpretations. The Company has elected to follow the disclosure-only alternative prescribed by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123"). Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. Compensation for options granted to non-employees has been determined in accordance with FAS 123 at the fair value of the equity instruments issued.

*Foreign Currency Translation*

The foreign subsidiaries functional currencies are their local currencies. The gains and losses resulting from translating the foreign subsidiaries' financial statements into US dollars have been reported in other comprehensive income (loss).

*Comprehensive Income (Loss)*

Comprehensive income (loss) consists of net loss and other comprehensive income (loss). Accumulated other comprehensive income (loss) presented in the consolidated balance sheets consists of the accumulated net unrealized gain (loss) on available-for-sale investments and foreign currency translation adjustments.

*Basic and Diluted Net Loss per Common Share*

Basic net loss per common share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per common share incorporates the incremental shares issued upon the assumed exercise of stock options and warrants, when dilutive. There is no difference between basic and diluted net loss per common share, as presented in the statement of operations, because all options and warrants are anti-dilutive. The total number of shares excluded was 5,041,375, 5,232,337 and 5,386,830 for the years ended December 31, 2001, 2000 and 1999, respectively.



**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

*New Accounting Standards*

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 141, "Business Combinations" ("Statement 141"). This Statement addresses financial accounting and reporting for business combinations. Statement 141 supersedes APB Opinion No. 16, Business Combinations (Opinion 16), and amends or supersedes a number of interpretations of that Opinion.

Statement 141 requires that (1) all business combinations be accounted for by a single method - the purchase method, (2) all intangible assets acquired in a business combination are to be recognized as assets apart from goodwill if they meet one of two criteria - the contractual-legal criterion or the separability criterion and (3) in addition to the disclosure requirements in Opinion 16, disclosure of the primary reasons for a business combination and the allocation of the purchase price paid to the assets acquired and liabilities assumed by major balance sheet caption. When the amounts of goodwill and intangible assets acquired are significant in relation to the purchase price paid, disclosure of other information about those assets is required, such as the amount of goodwill by reportable segment and the amount of the purchase price assigned to each major intangible asset class. The provisions of Statement 141 apply to all business combinations initiated after June 30, 2001. The Company adopted the provisions of Statement 141 as of July 1, 2001 for its Vaxis acquisition.

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangibles" ("Statement 142"). Under Statement 142, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Separable intangible assets that are not deemed to have an indefinite life will continue to be amortized over their estimated useful lives. Cellegy had recorded goodwill prior to December 31, 2001 related to the Quay acquisition. The adoption of this statement as of January 1, 2002 will decrease amortization expense by approximately \$97,000 per year for 2002 through 2009 as that goodwill will no longer be amortized.

In October 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("Statement 144"), which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. Statement 144 is effective for fiscal year beginning after January 1, 2002. The Company adopted Statement 144 as of January 1, 2002 and it does not expect that the adoption of the Statement will have a significant impact on the Company's financial position and results of operations.

*Reclassification*

Certain prior year balances have been reclassified for comparative purposes.

**2. Investments**

At December 31, 2001 and 2000, investments consist of the following:

	2001			2000		
	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Estimated Fair Value</u>	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Estimated Fair Value</u>
Corporate notes	\$ 6,678,378	\$ 79,642	\$ 6,758,020	\$ 999,836	\$ (8,879)	\$ 990,957
U.S. government notes	2,000,000	22,500	2,022,500	1,997,971	(18,391)	1,979,580
Commercial paper	2,000,000	—	2,000,000	3,500,000	—	3,500,000
	<u>\$10,678,378</u>	<u>\$102,142</u>	<u>\$10,780,520</u>	<u>\$6,497,807</u>	<u>\$(27,270)</u>	<u>\$6,470,537</u>

There have been no significant gross realized gains or losses on the sale of available-for-sale securities for the years ended December 31, 2001 and 2000. All available-for-sale securities at December 31, 2001 have maturities between twelve months through thirty six months from the balance sheet date.

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

**3. Property and Equipment**

Property and equipment consist of the following:

	<u>December 31,</u>	
	<u>2001</u>	<u>2000</u>
Furniture and fixtures .....	\$ 178,926	\$ 175,271
Office equipment .....	242,233	173,419
Laboratory equipment .....	742,882	662,506
Leasehold improvements .....	<u>2,917,075</u>	<u>2,919,390</u>
	4,081,116	3,930,586
Less accumulated depreciation and amortization	<u>(1,613,209)</u>	<u>(1,082,566)</u>
	<u>\$ 2,467,907</u>	<u>\$ 2,848,020</u>

**4. Note Payable**

In June 1998, the Company entered into a loan agreement with a bank to provide up to \$4.5 million through December 1999 with interest rates equal to the bank's prime rate plus one percentage point. The Company was required to repay the principal amount borrowed in 48 equal monthly installments ending in July 2003. In December 1999, the loan was amended to include a revolving credit line allowing the Company to pay down principal balances at any time or increase its borrowing up to a maximum of \$2.5 million at an interest rate equal to the bank's prime rate plus 0.75%. The fair value of the note payable is estimated based on current interest rates available to the Company for debt instruments with similar terms, degrees of risk, and remaining maturities. The carrying value of the note approximated its fair value. As of December 31, 2001, the note payable was fully repaid.

**5. Lease Commitments**

The Company leases its facilities and certain equipment under non-cancelable operating leases. Future minimum lease payments, net of future minimum sublease income at December 31, 2001, are as follows:

<u>Years ending December 31,</u>	<u>Lease</u> <u>Commitments</u>
2002 .....	1,487,927
2003 .....	1,595,976
2004 .....	1,726,431
2005 .....	1,885,690
2006 .....	2,082,131
Thereafter .....	<u>4,975,077</u>
	<u>\$13,753,232</u>

Rental expense, net of sublease income, was \$1,653,337, \$1,817,427, and \$1,815,502 for the years ended December 31, 2001, 2000, and 1999, respectively. The Company received \$896,896 in sublease income during the year ended December 31, 2001.

Restricted cash at December 31, 2001 and 2000 was approximately \$614,000 and secures two letters of credit related to our leases.

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

**6. 401(k) Plan**

The Company maintains a savings and retirement plan under Section 401(k) of the Internal Revenue Code. All employees are eligible to participate on their first day of employment with the Company. Under the plan, employees may contribute up to 15% of salaries per year subject to statutory limits. The Company provides a matching contribution equal to 25% of the employee's rate of contribution, up to a maximum contribution rate of 4% of the employee's annual salary. Expenses related to the plan for the years ended December 31, 2001, 2000 and 1999 were not significant.

**7. Acquisitions, Licenses and Other Agreements**

*Acquisitions*

In December 1997, the Company acquired patent and related intellectual property rights relating to Cellegesic (the "Agreement"), a topical product candidate for the treatment of anal fissures and hemorrhoids from Neptune Pharmaceuticals Corporation ("Neptune"). Under the terms of the Agreement, the Company issued 429,752 shares of common stock to Neptune on December 31, 1997. Upon the signing of a letter of intent on November 3, 1997, 33,057 shares of common stock were issued to Neptune. The Agreement calls for a series of additional payments, payable in shares of common stock, upon successful completion of various development milestones. Upon completion of milestones in 2001, the Company issued 104,113 shares of common stock valued at \$750,000 which has been recorded to research and development expenses. The remaining milestones, if achieved, would become payable over the next several years. Depending on several factors, including the market price of the common stock, such payments, which are fixed based on the Agreement, could result in the issuance of a significant number of shares of common stock. Future potential milestones payable in Cellegy common stock could result in the issuance of up to an additional 1,284,000 shares of Cellegy common stock based on the closing price of Cellegy stock at time of issuance. The Agreement does not provide for the payment by the Company of any future product royalties in connection with sales of Cellegesic.

In June 2000, Cellegy acquired all assets of Quay Pharmaceuticals Pty Ltd ("Quay"), an Australian pharmaceutical company producing Rectogesic, a drug similar to Cellegesic. The acquired assets consisted of Quay's inventory, purchased at Quay's cost at the time of acquisition, other tangible assets and purchased technology. The aggregate purchase price of \$1,835,000 included the aggregate value of the 169,224 shares of Cellegy common stock issued to Quay with a value of \$977,000, warrants to purchase 171,146 shares of common stock with a fair value of \$489,000, and cash payments of \$369,000. The purchase price was allocated to the net tangible assets of \$97,000, purchased technology of \$770,000, and goodwill of \$968,000, based on their estimated fair values on the acquisition date. Purchased technology and goodwill were being amortized over three and ten years, respectively. Following the adoption of FAS 142, the goodwill will no longer be amortized as of January 1, 2002. This transaction has been accounted for by the purchase method of accounting and accordingly, the approximated purchase price, shown above, has been allocated to the net assets acquired and the liabilities assumed based on the estimated fair values at the date of acquisition, with the excess of the purchase price over assigned asset values recorded as goodwill. The results of operating the acquired company have been included in the Company's consolidated financial statements since the acquisition date.

On November 27, 2001, Cellegy acquired Vaxis Therapeutics, a private Canadian company. Vaxis, renamed Cellegy Canada, is a small early stage research and development entity with access to pre-eminent scientists in the areas of sexual dysfunction, peripheral vascular disorders and nitric oxide pharmacology. The acquisition of this research is in line with the Company's goal of expanding its pipeline of products and protecting its patents. The purchase price of \$4.1 million consisted of 533,612 shares of our common stock and \$142,000 in cash. The purchase price was allocated as follows: \$350,000 to intangible assets, \$250,000 to tangible assets and \$3,500,000 to acquired in-process research and development.

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

The acquired technology was in an early stage of development that, as of the acquisition date, technological feasibility had not been reached and no alternative use existed. The assumptions used in determining the purchase price allocation was a discount rate of 37% on probability of expected cash flows. The intangible assets will be amortized over 5 years, the period of contractual obligation.

The Vaxis purchase agreement contains earn-out provisions for seven years that are based on commercial sales of any products developed by the Company or other revenues generated from the acquired research. Any contingent consideration paid in the future will be accounted for as a cost of earning the related revenues. The results of operations of the acquired company have been included in the Company's consolidated financial statements since the acquisition date.

Accumulated amortization of the Vaxis intangible assets at December 31, 2001 was \$6,000. The expected amortization expense for the next five years will be approximately \$68,800 per year.

*Other Agreements*

In October 1993, Cellegy entered into a license agreement with the University of California providing for an exclusive, worldwide, royalty bearing license, subject to customary government rights, for patent rights relating to barrier repair formulations jointly held by the University and Cellegy, in consideration of the issuance to the University of certain shares of preferred stock (which subsequently converted into shares of common stock) and the payment by Cellegy of a licensing fee. In March 1994, Cellegy entered into an exclusive, worldwide, royalty bearing license agreement with the University for patent rights, jointly held by the University of California and Cellegy, relating to certain drug delivery technologies, in consideration of the payment by Cellegy of a licensing fee, and an annual maintenance fee payable each year until Cellegy is commercially selling a licensed product. The Company is currently in the process of terminating the exclusive license for patent rights relating to drug delivery technologies. Following the termination, each of the joint owners of the patent rights will retain non-exclusive rights to the patents. The termination of these licenses reflects, in part, a shift towards development of products from the Company's own research efforts in areas believed to have the potential to be more commercially viable.

In August 2001, Cellegy announced a comprehensive agreement with Ventiv Integrated Solutions, a division of Ventiv Health, Inc. ("Ventiv"), a contract sales organization. Under the control and direction of Cellegy, Ventiv will provide certain sales and marketing services relating to the anticipated launch of Cellegesic, including a sales force of approximately 75 representatives. Ventiv will advance up to \$10 million, the amount and timing depending on various circumstances, to Cellegy to cover pre-launch and launch expenses. In return, the agreement provides Ventiv with a share of Cellegesic profits with Cellegy retaining more than 80% of product operating profit over the six-year life of the agreement. Activity under the agreement was minimal through December 31, 2001.

**8. Shareholders' Equity**

*Common Stock Private Placements*

In July 1999, Cellegy completed a private placement of 1,616,000 shares of common stock at a price of \$6.25 per share to a small group of institutional investors and the Company's President and Chief Executive Officer. Net proceeds were \$10,038,000.

In October 2000, Cellegy completed a private placement of 1,500,000 shares of common stock at a price of \$7.75 to a group of institutional investors. Net proceeds were \$11,602,473.

In June 2001, we completed a private placement of approximately 2,700,000 million shares of common stock at a price of \$5.60. Participants included two current investors, Baker/Tisch Investments and GMT Capital, as well as, five new investors. Net proceeds were \$15,199,206.

**Cellegy Pharmaceuticals, Inc.**  
(a development stage company)

**Notes to Consolidated Financial Statements — (Continued)**

*Preferred Stock*

The Company's Articles of Incorporation provide that the Company may issue up to 5,000,000 shares of preferred stock in one or more series. The Board of Directors is authorized to establish from time to time the numbers of shares to be included in, and the designation of, any such shares, to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon any wholly unissued series of preferred stock and to increase or decrease the number of shares of any such series without any further vote or action by the shareholders.

*Stock Option Plans*

In 1995, Cellegy adopted the Equity Incentive Plan (the "Plan") to provide for the issuance of incentive stock options and non-statutory stock options. When the Plan was established, Cellegy reserved 700,000 shares for issuance. From 1996 to 2001, an additional 2,750,000 shares were reserved for issuance under the Plan.

Activity under the Plan is summarized as follows:

	Shares Under Option	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance at January 1, 1999 .....	1,543,428	\$0.46- \$8.81	\$5.32
Granted .....	905,100	\$3.69- \$6.25	\$4.13
Canceled .....	(124,655)	\$3.62- \$8.81	\$5.14
Exercised .....	(136,110)	\$0.50- \$7.25	\$4.57
Balance at December 31, 1999 .....	2,187,763	\$0.50- \$8.81	\$4.82
Granted .....	191,350	\$3.31- \$9.00	\$6.21
Canceled .....	(132,718)	\$3.00- \$9.00	\$5.35
Exercised .....	(95,754)	\$1.81- \$6.25	\$3.97
Balance at December 31, 2000 .....	2,150,641	\$0.50- \$9.00	\$5.00
Granted .....	476,000	\$4.56- \$15.00	\$7.96
Canceled .....	(123,634)	\$3.69- \$7.87	\$5.71
Exercised .....	(60,803)	\$1.81- \$4.62	\$3.35
Balance at December 31, 2001 .....	2,442,204	\$0.50- \$15.00	\$5.59

At December 31, 2001, options to purchase 1,576,834 shares of common stock were vested and exercisable at exercise prices ranging from \$0.46 to \$15.00 per share. At December 31, 2001, 519,638 options to purchase shares of common stock were available for future option grants under the Plan.

The following table summarizes information about stock options outstanding and exercisable related to the Plan at December 31, 2001:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Outstanding at December 31, 2001	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable at December 31, 2001	Weighted Average Exercise Price
\$ 0.46 - \$ 3.88	824,424	6.7 years	\$3.55	625,358	\$3.49
\$ 4.00 - \$ 6.99	1,007,180	6.7 years	\$5.50	565,701	\$5.20
\$ 7.00 - \$15.00	610,600	7.3 years	\$8.49	385,775	\$7.50
Total	<u>2,442,204</u>	6.9 years	\$5.59	<u>1,576,834</u>	\$5.08

**Cellegy Pharmaceuticals, Inc.**  
(a development stage company)

**Notes to Consolidated Financial Statements — (Continued)**

*Director's Stock Option Plan*

In 1995, Cellegy adopted the 1995 Directors' Stock Option Plan (the "Directors' Plan") to provide for the issuance of non-qualified stock options to eligible outside Directors. When the plan was established, Cellegy reserved 150,000 shares for issuance. During 2000, Cellegy reserved an additional 100,000 shares for issuance under the Directors' Plan.

Activity under the Directors' Plan is summarized as follows:

	Shares Under Option	Price Range Per Share	Weighted Average Exercise Price
Balance at January 1, 1999 .....	114,000	\$3.25-\$8.50	\$5.20
Granted .....	32,000	\$5.00	\$5.00
Cancelled .....	(12,083)	\$3.25-\$8.50	\$5.46
Exercised .....	(21,417)	\$3.25-\$8.50	\$5.12
Balance at December 31, 1999 .....	112,500	\$3.25-\$8.50	\$5.13
Granted .....	70,000	\$4.81	\$4.81
Balance at December 31, 2000 .....	182,500	\$3.25-\$8.50	\$5.01
Granted .....	46,000	\$5.50-\$6.50	\$5.85
Balance at December 31, 2001 .....	<u>228,500</u>	\$3.25-\$8.50	\$7.26

At December 31, 2001, options to purchase 134,999 shares of common stock were vested and exercisable at exercise prices ranging from \$3.25 to \$8.50 per share. At December 31, 2001, options to purchase 833 shares of common stock were available for future option grants under the Directors' Plan.

The following table summarizes information about stock options outstanding and exercisable related to the Directors' Plan at December 31, 2001:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Outstanding at December 31, 2001	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable at December 31, 2001	Weighted Average Exercise Price
\$3.25	4,000	5.3 years	\$3.25	4,000	\$3.25
\$4.50 - \$5.50	206,500	7.1 years	\$5.08	129,999	\$5.07
\$6.50 - \$8.50	18,000	8.9 years	\$6.72	1,000	\$8.50
Total	<u>228,500</u>	7.3 years	\$5.18	<u>134,999</u>	\$5.04

The Company has elected to follow APB Opinion No. 25 and related interpretations in accounting for its stock options since, as discussed below, the alternative fair market value accounting provided for under FAS 123 requires use of option valuation models that were not developed for use in valuing stock options. Under APB Opinion No. 25, if the exercise price of the Company's stock options is equal to the market price of the underlying stock on the date of grant, no compensation expense is recognized related to employee or director grants.

Pro forma information regarding net loss and net loss per common share is required by FAS 123, which requires that the information be determined as if the Company has accounted for its common stock options granted under the fair market value method. The fair market value of options granted has been estimated at the date of the grant using a Black-Scholes option pricing model.

**Cellegy Pharmaceuticals, Inc.**  
(a development stage company)

**Notes to Consolidated Financial Statements — (Continued)**

The Company valued its options using the following weighted average assumptions for the years ended December 31, 2001, 2000 and 1999:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Risk-free interest rate .....	3.5%	6.00%	5.54%
Dividend yield .....	0%	0%	0%
Volatility .....	0.60	0.91	0.83
Expected life of options in years .....	4.3	4.3	3.7

The Black-Scholes option pricing model was developed for use in estimating the fair market value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair market value estimate. In management's opinion, the existing models do not necessarily provide a reliable single measure of the fair market value of its stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information for the years ended December 31 are as follows:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Net loss as reported .....	\$(19,464,723)	\$(11,418,213)	\$ (9,301,156)
Pro forma net loss .....	\$(22,152,474)	\$(13,105,202)	\$(10,612,716)
Basic and diluted net loss as reported .....	\$ (1.26)	\$ (0.91)	\$ (0.85)
Pro forma basic and diluted net loss per share applicable to common shareholders ....	\$ (1.43)	\$ (1.04)	\$ (0.97)

The weighted average grant date fair value of options granted during the years ended December 31, 2001, 2000, and 1999 was \$5.33, \$4.30 and \$2.47, respectively. The weighted average remaining contractual life of those options is 6.8 years, 7.2 years and 8.1 years during the years ended December 31, 2001, 2000 and 1999, respectively.

The effects of applying FAS 123 pro forma disclosures are not likely to be representative of the effects on reported net loss for future years.

*Shares reserved*

As of December 31, 2001, the Company has reserved shares of common stock for future issuance as follows:

Warrants .....	635,700
Stock Option Plans .....	3,191,175
Neptune Agreement .....	<u>1,285,000</u>
Total .....	<u>5,041,375</u>

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

**9. Income Taxes**

At December 31, 2001 the Company had net operating loss carryforwards of approximately \$58,000,000 and \$10,000,000 for federal and state purposes, respectively. The federal net operating loss carryforwards expire between the years 2004 and 2021. The state net operating loss carryforwards expire between the years 2002 and 2005. At December 31, 2001, the Company also had research and development credit carryforwards of approximately \$1,300,000 and \$900,000 for federal and state purposes, respectively. The federal credits expire between the years 2006 and 2021. Pursuant to the "change in ownership" provisions of the Tax Reform Act of 1986, utilization of the Company's net operating loss and research and development tax credit carryforwards may be limited if a cumulative change of ownership of more than 50% occurs within any three-year period. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax liabilities and assets are as follows

	December 31,	
	<u>2001</u>	<u>2000</u>
Deferred tax assets		
Net operating loss carryforwards .....	\$ 20,200,000	\$ 15,400,000
Credit carryforwards .....	1,900,000	1,600,000
Capitalized intangibles .....	1,500,000	1,200,000
Other, net .....	<u>300,000</u>	<u>400,000</u>
Total deferred tax assets .....	24,200,000	18,600,000
Valuation allowance .....	<u>(24,200,000)</u>	<u>(18,600,000)</u>
Net deferred tax assets .....	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance for deferred tax assets for 2001, 2000, and 1999 increased by approximately \$5,700,000, \$3,500,000, and \$3,800,000, respectively.

**10. Segment Reporting**

The Company has two business segments: pharmaceuticals and cosmeceuticals. Pharmaceuticals include primarily research and clinical development expenses for potential prescription products to be marketed directly by Cellegy or through corporate partners. Current pharmaceutical revenues consist primarily of Rectogesic sales in Australia. The Company expects to complete other corporate collaborations in the future for a number of its potential pharmaceutical products, which may result in milestones, development funding and royalties on sales. Cellegy expects to generate future revenues on potential products it intends to self-market.

The cosmeceutical business segment includes primarily development expenses for non-prescription anti-aging products. Using related technologies, Cellegy is currently incurring development expenses and receiving all of its product sales from one customer, Gryphon Development, Inc., which is selling one of the company's products, exclusively in the United States, through a major specialty retailer.

Cellegy allocates its revenues and operating expenses to each business segment, but does not assess segment performance or allocate resources based on a segment's assets and, therefore, asset depreciation and amortization and capital expenditures are not reported by segment. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

The Company's segments are business units that will, in some cases, distribute products to different types of customers through different marketing programs. The potential future sales of cosmeceutical products requires a significantly different marketing effort than sales of pharmaceutical products to



**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

physicians and other traditional pharmaceutical distribution channels. Pharmaceutical products require more extensive clinical testing and ultimately regulatory approval by the FDA and other worldwide health registration agencies, requiring a more extensive level of development, manufacturing and compliance than a cosmeceutical product.

The following table contains information regarding revenues and operating income (loss) of each business segment for the years ended December 31, 2001, 2000, and 1999:

	<u>Years ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Revenues:			
Pharmaceuticals .....	\$ 217,439	\$ 196,434	\$ 147,279
Cosmeceuticals .....	660,052	1,389,189	897,859
	<u>\$ 877,491</u>	<u>\$ 1,585,623</u>	<u>\$ 1,045,138</u>
Operating Income (Loss):			
Pharmaceuticals .....	\$(21,021,796)	\$(13,114,538)	\$(9,888,212)
Cosmeceuticals .....	52,427	1,127,139	85,914
	<u>\$(20,969,369)</u>	<u>\$(11,987,399)</u>	<u>\$(9,802,298)</u>

*Revenue from Major Customer*

Revenues from product sales to one customer represented approximately 75%, 88%, and 86% of consolidated revenue for 2001, 2000 and 1999, respectively.

Total assets were minimal for the cosmeceutical segment.

*Geographic data*

Approximately 25% of our total revenues are from sales of Rectogesic in Australia. All other sales are in the United States.

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

**11. Related Party Transactions**

We have paid fees to the Company's board members for their services on the board, audit committee and compensation committee. The total fees paid to these directors during 2001, 2000 and 1999 were \$57,750, \$46,500 and \$30,000.

Additional consulting fees were paid to two board members based on a consulting agreement. These were \$80,000 and \$66,000 for 2001 and 2000, respectively.

We have also recognized \$100,888 in compensation expense during 2001 for a consulting agreement with a current board member. The Company issued stock options to this board member for his consulting services.

**12. Quarterly Financial Data ( unaudited )**

(amounts in thousands except per share data)

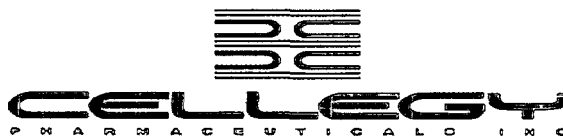
2001	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total</u>
Total revenue .....	\$ 41	\$ 53	\$ 265	\$ 518	\$ 877
Operating loss .....	(4,206)	(4,352)	(4,182)	(8,229)	(20,969)
Net loss .....	(3,777)	(4,156)	(3,871)	(7,661)	(19,465)
Basic & diluted net loss per common share ....	\$ (0.27)	\$ (0.29)	\$ (0.23)	\$ (0.47)	\$ (1.26)
2000	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total</u>
Total revenue .....	\$ 530	\$ 132	\$ 626	\$ 298	\$ 1,586
Operating loss .....	(1,981)	(2,894)	(3,122)	(3,990)	(11,987)
Net loss .....	(1,915)	(2,690)	(3,059)	(3,754)	(11,418)
Basic & diluted net loss per common share ....	\$ (0.16)	\$ (0.22)	\$ (0.25)	\$ (0.28)	\$ (0.91)

**CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-06065), the Registration Statement (Form S-8 No. 333-32301), and the Registration Statement (Form S-8 No. 333-60343) and the Registration Statement (Form S-8 No. 333-42840) pertaining to the 1992 Stock Option Plan, the 1995 Equity Incentive Plan, and the 1995 Directors' Stock Option Plan, and in the Registration Statement (Form S-3 No. 33-11457), the Registration Statement (Form S-3 No. 333-36057), the Registration Statement (Form S-3 No. 333-46087), the Registration Statement (Form S-3 No. 333-86193), the Registration Statement (Form S-3 No. 333-49466) and the Registration Statement (Form S-3 No. 333-64864) of Cellegy Pharmaceuticals, Inc. of our report dated February 9, 2002, with respect to the consolidated financial statements of Cellegy Pharmaceuticals, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2001 filed with the Securities and Exchange Commission.

Palo Alto, California  
March 7, 2002

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April 18, 2002

Dear Shareholder:

2001 was a year of significant clinical and strategic accomplishments for Cellegy Pharmaceuticals. While the financial markets and the pharmaceutical/biotechnology sector came under pressure, we ended the year fundamentally strong and well positioned as a product-focused specialty biopharmaceutical company. We have two exciting products that are in advanced stages of development, a full pipeline of product candidates following closely behind, and a strong management team committed to moving us successfully into the commercial arena.

Cellegy's two most advanced products are Cellegesic<sup>TM</sup> (nitroglycerin ointment) and Tostrex<sup>TM</sup> (testosterone gel). Cellegesic, developed for the control of pain associated with anal fissures, is currently awaiting the FDA's decision on marketing approvability in the United States. Cellegy's international version of Cellegesic, called Rectogesic<sup>TM</sup>, is being successfully marketed in Australia and has been submitted for regulatory approval in several other international markets.

Tostrex, our testosterone gel product, is for the treatment of male hypogonadism, a condition that results in decreased energy, libido and muscle mass. Late last year, we successfully completed a Phase III clinical trial with Tostrex and we plan to submit a New Drug Application (NDA) for domestic marketing approval during this quarter. A third product, Tostrelle<sup>TM</sup> (testosterone gel), for the treatment of female sexual dysfunction, is undergoing a Phase II/III clinical study in menopausal women.

The Company's year end cash position remained strong at nearly \$17.2 million, based in part on the completion of a \$15.4 million private placement of our common stock with institutional investors in June 2001.

#### *Expanding through Acquisitions*

In November 2001, Cellegy acquired Vaxis Therapeutics Corporation, a private Canadian company based in Kingston, Ontario, now called Cellegy Canada. This acquisition expanded our patent portfolio and pipeline of products for the treatment of sexual dysfunction in males and females. In addition to sexual dysfunction, the Vaxis product pipeline and patents consists of nitroglycerin and other nitric oxide donors for the treatment of prostate cancer, peripheral vascular disorders including Raynaud's Disease, Restless Leg Syndrome, and other potential indications.

The Vaxis acquisition provided us with access to top researchers in our areas of interest. Jeremy Heaton, M.D., Michael Adams, Ph.D. and Charles Graham, Ph.D. are each recognized as experts in their respective fields and are now Cellegy consultants. Drs. Heaton and Adams, for example, were the discoverers of the use of apomorphine for the treatment of male erectile dysfunction, a successfully marketed product in Europe. Dr. Jim Banting, who joined us as Director of Business Development, is an accomplished scientist in the field of peripheral vascular disorders and is related to the late Dr. Frederick Banting, a co-discoverer of insulin.

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### *Preparing for Commercialization*

Our core marketing and sales team has recently come together under the recognized leadership of Michael Miller, former head of ALZA's Urology Division, its largest and most profitable business unit. As Cellegy's Vice President, Commercial Operations, Mike is responsible for marketing, sales and manufacturing. Working with Mike is an experienced, top-notch group capable of successfully launching Cellegy's novel products, once approved.

During 2001, we put in place an innovative agreement with Ventiv Health, a major contract sales organization, to jointly prepare for the domestic launch of Cellegesic under the guidance of our marketing and sales team. Preparations are well under way, and assuming a timely and favorable regulatory review, we expect to launch Cellegesic through our own specialty sales force in the United States.

### *Cellegesic for Anal Fissures and Hemorrhoids*

Cellegy's lead product candidate, Cellegesic, is under review by the FDA for the treatment of anal fissures, a painful condition which, in the absence of approved drug therapy, often requires surgery. The New Drug Application was filed with the FDA in June 2001.

Cellegy is also conducting two Phase II clinical trials to treat various symptoms of hemorrhoids. We plan to publish the study results and, if successful, initiate pivotal Phase III trials for the purpose of seeking FDA approval for the treatment of this widespread disorder. It is estimated that at least 9 million people suffer from hemorrhoids in the United States alone. Based on published market research, the revenue potential in the United States, Europe and Japan for products effective in the treatment of anal fissures and hemorrhoids is in excess of \$2 billion per year.

We have effectively utilized the Australian Therapeutic Goods Administration's approval package for Rectogesic to file for marketing approval in the United Kingdom and several Pacific Rim countries including South Korea, Taiwan, Hong Kong and New Zealand. In addition, we have modified the Cellegesic NDA submission and filed it in Canada. We will continue to use these regulatory packages in other major markets during the course of this year.

### *Tostrex (Testosterone Gel) for Men*

Late last year, we successfully completed a multi-center Phase III clinical study in the United States which demonstrated that Tostrex can reliably and safely restore normal testosterone levels in hypogonadal men. We expect to file an NDA on Tostrex during the second quarter of this year and, assuming a positive FDA review, launch Tostrex as our second major commercial entry in 2003.

There are an estimated 5 million hypogonadal men in the United States who have clinically deficient testosterone levels and many millions more who suffer from decreased libido and energy levels caused by an age-related decline in testosterone levels. The currently marketed transdermal testosterone patches are unsightly and often cause irritation, drawbacks which have limited their sales. Another testosterone gel product was successfully launched in the United States and has quickly generated significant market penetration, validating our belief in the superiority of the transdermal gel approach to hormone replacement therapy.

We believe Tostrex has competitive advantages over the other gel product, including a more patient-friendly metered dosing system which allows physicians to easily adjust (titrate) doses to optimize individual patient requirements. We expect that, when available, Tostrex will effectively compete with the other transdermal products and further expand the male testosterone replacement therapy market in the United States.

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### *Tostrelle (Testosterone Gel) for Women*

Women are also dependent on testosterone, albeit at lower levels than men. Testosterone deficiency contributes to a wide range of symptoms including sexual dysfunction (lowered libido), reduced muscle mass, lowered energy levels, and reduced sense of well-being. Tostrelle will also be packaged in a metered dosing system with user-friendly dosing advantages similar to Tostrex. We believe our product may be one of the first to compete in this large and growing, but as yet untapped, market of 11 to 15 million testosterone deficient women in the United States.

We have successfully completed two Phase I/II trials in which we reproducibly and safely achieved targeted testosterone levels in both naturally menopausal and surgically menopausal women. These trials demonstrated that bioavailable testosterone levels, similar to those in young women, could be reliably achieved in women taking various forms of hormone replacement therapy. After meeting with the FDA, we recently initiated a Phase II/III clinical trial using Tostrelle for the treatment of sexual dysfunction in menopausal women. The advanced trial will measure a broad range of clinical benefits expected to be achieved by restoring testosterone levels in menopausal women to those of healthy menstruating women.

### *Looking Forward*

This year is an important transition year for Cellegy and you, our shareholders. We currently have two exciting, high potential products which have successfully completed clinical testing, are moving through the regulatory process and, we hope, will be approved for commercialization. We have gained valuable marketing experience from Rectogesic, which has captured an important share of the anal fissure market in Australia and we are making great strides in preparing ourselves for successful entry into the United States market.

We are diligently working to complete partnering arrangements and other collaborations for the commercialization of Cellegesic and Tostrex overseas and to permit promotion of these products to appropriate physician groups domestically. We also plan to continue to implement our strategy to in-license late-stage products and acquire companies with complimentary products to fill our commercial and development pipeline. The Vaxis acquisition last year is the most recent example of this strategy in action.

In closing, we would like to re-affirm that our primary objective is to increase shareholder value through sound business decision making and appropriate planning. We believe that the markets for Cellegy's products offer tremendous potential and, if successful with regulatory approvals and marketing, we will be well positioned to take advantage of heightened investor interest in the specialty biopharmaceutical sector. All of us at Cellegy are working hard to ensure that this value is realized by our stockholders. I look forward to your continued support as we strive to achieve our objectives.



K. Michael Forrest

*This letter and the Annual Report contain forward-looking statements which reflect management's intentions, hopes, beliefs, expectations or predictions for the future. Actual results with regard to the outcomes of regulatory reviews, particularly for Cellegesic, are subject to considerable risk and uncertainty. The FDA or other regulatory agencies could, among other things, delay approval or not approve our products. Clinical trial results and commercialization plans could change materially from those projected in this letter. Statements made in this letter should be read in conjunction with the Company's 2001 Annual Report accompanying this letter.*

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## **BOARD OF DIRECTORS**

K. Michael Forrest  
Chairman, President and CEO

Felix J. Baker, Ph.D.  
Managing Partner  
Baker/Tisch Investments

Julian C. Baker  
Managing Partner  
Baker/Tisch Investments

Jack L. Bowman  
Former Group Chairman  
Johnson & Johnson

Tobi B. Klar, M.D.  
Associate Clinical Professor Dermatology  
Albert Einstein Hospital Center

Ronald J. Saldarini, Ph.D.  
Former President  
Wyeth-Lederle Vaccines

Alan A. Steigrod  
Managing Director  
Newport HealthCare Ventures

Carl R. Thornfeldt, M.D.  
Founder and Clinical Dermatologist

Larry J. Wells  
President  
Wells Investment Group

## **GENERAL COUNSEL**

Fenwick and West LLP  
Palo Alto, California

## **PATENT COUNSEL**

Townsend and Townsend and Crew LLP  
San Francisco, California

## **INDEPENDENT AUDITORS**

Ernst & Young LLP  
Palo Alto, California

## **TRANSFER AGENT**

Mellon Investor Services  
Phone: (800) 522-6645  
[www.mellon-investor.com](http://www.mellon-investor.com)

## **OFFICERS**

K. Michael Forrest  
Chairman, President and CEO

Daniel L. Azarnoff, M.D.  
Senior Vice President, Medical and  
Regulatory Affairs

John J. Chandler  
Vice President, Corporate Development

A. Richard Juelis  
Vice President, Finance & CFO

Michael P. Miller  
Vice President, Commercial Operations

## **SHAREHOLDER INQUIRIES**

K. Michael Forrest  
Chairman, President and CEO  
(650) 616-2206

A. Richard Juelis  
Vice President, Finance and CFO  
(650) 616-2210

## **ANNUAL MEETING**

Scheduled for Wednesday, June 5, 2002  
at 8:30 a.m. at our Corporate Office.



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[www.cellegy.com](http://www.cellegy.com)  
Nasdaq: CLGY

To receive a copy of the Company's Annual Report on Form 10-K or other financial materials without charge, you may contact our Corporate Secretary at the above address.

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